

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

STEVEN HILL, Derivatively On Behalf Of  
JOHNSON & JOHNSON,

Plaintiff,

v.

ALEX GORSKY, ANNE M. MULCAHY,  
CHARLES PRINCE, WILLIAM D. PEREZ, IAN  
E. L. DAVIS, RONALD A. WILLIAMS, A.  
EUGENE WASHINGTON, MARK B.  
MCCLELLAN, D. SCOTT DAVIS, MARY C.  
BECKERLE, CAROL GOODRICH, MICHAEL  
E. SNEED, JOAN CASALVIERI, and TARA  
GLASGOW,

Defendants,

and,

JOHNSON & JOHNSON,

Nominal Defendant.

Case No.:20-774

**SHAREHOLDER DERIVATIVE  
COMPLAINT**

Plaintiff Steven Hill (“Plaintiff”), by and through his undersigned counsel, derivatively on behalf of Nominal Defendant Johnson & Johnson (“J&J” or the “Company”), submits this Verified Shareholder Derivative Complaint (the “Complaint”). Plaintiff’s allegations are based upon his personal knowledge as to himself and his own acts, and upon information and belief, developed from the investigation and analysis by Plaintiff’s counsel, including a review of publicly available information, including filings by the Company with the U.S. Securities and Exchange Commission (“SEC”), press releases, news reports, analyst reports, investor conference transcripts, publicly available filings in lawsuits, and matters of public record.

**NATURE OF THE ACTION**

1. This is a shareholder derivative action brought in the right, and for the benefit, of the Company against certain of its officers and directors seeking to remedy Defendants' (as defined below) breach of fiduciary duties from February 22, 2013 to the present ("Relevant Period").

2. Prior to and during the Relevant Period, Defendants (defined below) engaged in a scheme to defraud investors and issued false and misleading statements in order to conceal the truth regarding the Company's talc and Baby Powder. Specifically, Defendants intentionally concealed that: (i) the Company's talc and talcum powder products were contaminated with asbestos, as the Company had been repeatedly informed; (ii) the Company had attempted to find ways to remove asbestos minerals from its talc; (iii) the Company purposely avoided the use of testing methods that could detect the asbestos present in the Company's talc, and (iv) the Company had influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation.

3. During the Relevant Period, the Company was facing product liability litigation over its Baby Powder and the product's alleged association with ovarian cancer. As Defendants knew, Johnson's Baby Powder was crucial to "the positive J&J name in the public mind" and critical to the Company's reputation as a trustworthy company. With the Company's flagship product and very identity at stake, Defendants made material misstatements and omissions regarding the Company's talc and talcum powder products, its true litigation and reputational exposure, and its management and decision-making processes.

4. During the Relevant Period, Defendants repeatedly claimed that the Company's talc products had "a long history of safe use" and promised that the products are, and always had been, free of asbestos. But while Defendants claimed that the Company's cosmetic powder products have been safe "[f]or over 100 years," and that "regular testing conducted since the 1970s" had confirmed

the absence of asbestos, Defendants knew that the Company's talc and talcum powders had long been contaminated with asbestos. In fact, from at least 1971 to the 2000s, the Company's raw talc and finished powders repeatedly tested positive for asbestos, and Company executives, mine managers, scientists, doctors and lawyers discussed the asbestos contamination, but failed to disclose it to regulators or the public.

5. Defendants also concealed what they recognized internally, that talc had not been used safely for over 100 years, that some scientific sources "could be interpreted as suggesting a causal effect" between ovarian cancer and talc, and that "[e]ven some of the studies [J&J] cite[d] send mixed messages." And while Defendants assured investors that the Company's "talc products are, and always have been, free of asbestos," internally the Company admitted that "we cannot say 'always.'"

6. Defendants' assurances regarding the Company's asbestos testing were also false and misleading, as the Company's asbestos testing "since the 1970s" had not "confirmed" that the talc or powders were "asbestos free." While Defendants represented during the Relevant Period that the Company used "a sophisticated battery of tests designed to ensure . . . safety," the truth was that the Company intentionally avoided sophisticated "concentration techniques" for testing, which the Company knew were necessary for finding asbestos in talc. In fact, the Company's own consultant had informed the Company that "larger amounts of sample" must be tested to find asbestos, and that "preconcentrat[ing] the impurities prior to examination" "was considered essential to the success of any suggested procedure." But because the Company knew that a concentration method would show asbestos in the Company's talc, the Company determined that the method "may be too sensitive," leading the Company to "avoid promotion of this approach," as the Company "really want[ed] to exclude concentration techniques." Indeed, when the U.S. Food and Drug Administration ("FDA")

later requested proposals for ““sophisticated”” testing techniques that would lead to “concentration procedures,” the Company found it to be ““disturbing,”” as the techniques would make “many talcs on all markets . . . hard pressed in supporting purity claims.”

7. Throughout the Relevant Period, Defendants also misrepresented the Company’s internal policies and concealed the Company’s long history of infiltrating and undermining regulatory processes. According to Defendants, the Company “has always taken questions about the safety” of Johnson’s Baby Powder “extremely seriously,” particularly because it is a product “that families have trusted for generations.” In truth, the Company had lied to the FDA about its talc and undermined the activities of certain public health officials and doctors it branded as ““Antagonistic Personalities.””

8. Rather than being “guided by the medical facts and science when it comes to [its] products,” or “always put[ting] . . . safety first in everything that [it does],” the Company has long been driven by the objective of protecting the (false) image of safety of Johnson’s Baby Powder. Indeed, the Company strove “to neutralize [and] hold in check data . . . generated by investigators who question the safety of talc.” And while a December 1977 – January 1978 report illustrates the Company’s knowledge that both its Baby Powder and talc contained asbestos, that same report also shows that the Company had set out “[t]o monitor and defend against consumerist, scientific and regulatory attitudes/trends which could impact adversely on the safety image and marketability of cosmetic talcs.” Even while the Company knew that its talc and Baby Powder contained unsafe asbestos, it had nonetheless set forth on a mission “[t]o generate or provide . . . data to support and reinforce the safety of our baby powder.”

9. In September 2017, the Company faced its first trial alleging the presence of asbestos in Johnson’s Baby Powder, brought by a plaintiff-consumer with mesothelioma. On September 21,

2017, *Bloomberg* reported on documents from the 1970s that had been unsealed in the talc litigation, reporting that “J&J was alerted to [the] risk of asbestos in talc in [the] ‘70s.” At the same time, however, the article reported that the Company documents showed “tests of its talc stretching back to at least 1972 found no trace of asbestos,” and reiterated defendants’ promise that the Company’s “talc products are, and always have been, free of asbestos.” The *Bloomberg* article also quoted defendants as claiming that “[h]istorical testing of samples by the FDA” as well as ““numerous independent”” laboratories and scientists ““have all confirmed the absence of asbestos in our talc products.”” Defendants’ vigorous denials in the *Bloomberg* article (and throughout the Relevant Period) prevented investors from learning the truth and maintained inflation in the Company’s stock price. But through a series of partial disclosures the relevant truth would leak out and cause the stock price to decline.

10. For example, on February 5, 2018, investors were informed that “experts [were] anticipating the release of numerous damaging internal company documents” from the Company relating to asbestos in its Baby Powder. The Company’s stock declined over 5% in response, and numerous financial analysts and commentators attributed the decline to the news. But Defendants continued to defend the Company’s talc products, falsely reassuring consumers and investors once again that the products “are, and always have been, free of asbestos” and that this was shown by ““decades of monitoring, testing and regulation dating back to the 1970s.””

11. Then, on July 12, 2018, investors were stunned when a jury awarded a \$4.69 billion verdict to 22 plaintiffs alleging that asbestos in the Company’s products caused their ovarian cancer. As numerous news outlets reported, the Company’s stock price dropped in response to the verdict. In order to continue their fraudulent scheme, and stem the decline in the Company’s stock price, Defendants claimed that the verdict “was the product of a fundamentally unfair process” in which

“the evidence in the case was simply overwhelmed by the prejudice” the Company purportedly suffered.

12. Finally, on December 14, 2018, *Reuters* published a bombshell report entitled “Powder Keg: Johnson & Johnson knew for decades that asbestos lurked in its Baby Powder” (the “Reuters report”). The *Reuters* report disclosed new information and new analysis, including internal J&J documents “reported to the public for the first time.” In addition to revealing the Company’s knowledge of asbestos contamination, *Reuters* disclosed the Company’s “successful efforts to influence U.S. regulators’ plans to limit asbestos in cosmetic talc products and scientific research on the health effects of talc.” The report also detailed how the Company had purposely avoided concentration techniques and how the Company knew that such methods could find asbestos in its talc products. In response to the *Reuters* report, the Company’s stock plunged 10%, wiping away nearly \$40 billion in market value in a single day.

13. In response to the *Reuters* report’s revelations, the U.S. government has taken action. For example, on December 14, 2018, U.S. Senator Ed Markey requested that the FDA “immediately investigate these allegations and determine whether Johnson & Johnson’s actions have placed at risk the public’s health and safety.” On January 28, 2019, U.S. Senator Patty Murray sent the Company a letter requesting documents related to the “alleged decades-long effort by Johnson & Johnson to potentially mislead regulators and consumers about the safety” of Johnson’s Baby Powder. And, on February 20, 2019, the Company disclosed that it had received “preliminary inquiries and subpoenas” from the U.S. Department of Justice (“DOJ”) and the U.S. Securities and Exchange Commission (“SEC”) to produce documents and the safety of its talc-containing products.

### **JURISDICTION AND VENUE**

14. Pursuant to 28 U.S.C. § 1331 and section 27 of the Securities Exchange Act of 1934 (the “Exchange Act”), this Court has jurisdiction over the claims asserted herein for violations of sections 10(b) of the Exchange Act. This Court has supplemental jurisdiction over the remaining claims under 28 U.S.C. § 1367.

15. This Court has jurisdiction over each defendant named herein because each defendant is either a corporation that conducts business in and maintains operations in this District or is an individual who has sufficient minimum contacts with this District to render the exercise of jurisdiction by the District courts permissible under traditional notions of fair play and substantial justice.

16. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) because Nominal Defendant J&J is a New Jersey corporation with principal executive offices located at One Johnson & Johnson Plaza, New Brunswick, New Jersey.

### **THE PARTIES**

#### **Plaintiff**

17. *Plaintiff Steven Hill* (“Hill”) is, and was at relevant times, a shareholder of J&J. Plaintiff Hill purchased his J&J stock in 2008 and still holds his J&J shares today. Plaintiff will fairly and adequately represent the interests of the shareholders in enforcing the rights of the corporation.

#### **Nominal Defendant**

18. Nominal Defendant J&J is a New Jersey corporation with principal executive offices located at One Johnson & Johnson Plaza, New Brunswick, New Jersey.

#### **Director Defendants**

19. **Defendant Alex Gorsky** (“Gorsky”) is the Company’s Chairman of the Board, Chief Executive Officer (“CEO”), Chairman of the Executive Committee, and a director. Defendant Gorsky was also the Company’s Vice Chairman of the Executive Committee from January 2011 to April 2012; a Member of the Executive Committee from January 2009 to January 2011; Worldwide Chairman, Medical Devices and Diagnostics Group from September 2009 to January 2011; Worldwide Chairman, Surgical Care Group from January 2009 to September 2009; Company Group Chairman and Worldwide Franchise Chairman for Ethicon, Inc., a subsidiary of the Company, from 2008 to January 2009; and held other various positions of increasing responsibility at the Company and its subsidiaries from 1988 to 2004. Defendant Gorsky is a named defendant in the Securities Class Action complaint entitled *Hall v. Johnson & Johnson, et. al.*, No. 3:18-cv-01833-FLW-TJB (D. N.J.) (“Securities Class Action”).

20. **Defendant Anne M. Mulcahy** (“Mulcahy”) is the Company’s Lead Director and has been since December 2012 and a director since October 2009. Defendant Mulcahy is a member of the Company’s Audit Committee since at least March 2013.

21. **Defendant Charles Prince** (“Prince”) is a Company director since February 2006. Defendant Prince is the Chairman and a member of the Company’s Regulatory Compliance Committee and has been since at least March 2017.

22. **Defendant William D. Perez** (“Perez”) is a Company director since June 2007. Defendant Perez is a member of the Company’s Audit Committee since at least March 2017.

23. **Defendant Ian E. L. Davis** (“I. Davis”) is a Company director since July 2010. Defendant I. Davis is a member of the Company’s Audit Committee since at least March 2012, and a member of the Regulatory Compliance Committee since at least March 2017. Defendant I. Davis



was previously a member of the Company's Public Policy Advisory Committee in at least March 2012.

24. ***Defendant Ronald A. Williams*** ("Williams") is a Company director since June 2011. Defendant Williams was previously the Chair of the Company's Regulatory Compliance Committee in at least March 2016, a member of that committee from at least March 2013 to at least March 2016, and a member of the Public Policy Advisory Committee in at least March 2012.

25. ***Defendant A. Eugene Washington*** ("Washington") is a Company director since November 2012. Defendant Washington was previously a member of the Company's Regulatory Compliance Committee from at least March 2013 to at least March 2014. Upon information and belief, Defendant Washington is a citizen of North Carolina.

26. ***Defendant Mark B. McClellan*** ("McClellan") is a Company director since October 2013. Defendant McClellan is a member of the Company's Regulatory Compliance Committee and has been since at least March 2014.

27. ***Defendant D. Scott Davis*** ("S. Davis") is a Company director and has been since June 2014. Defendant S. Davis is the Chair of the Company's Audit Committee since at least March 2016, and a member of that committee and has been since at least March 2015. Defendant S. Davis was previously a member of the Company's Regulatory Compliance Committee from at least March 2015 to at least March 2016.

28. ***Defendant Mary C. Beckerle*** ("Beckerle") is a Company director since June 2015. Defendant Beckerle is a member of the Company's Regulatory Compliance Committee since at least March 2017.

**Officer Defendants**

29. ***Defendant Carol Goodrich*** (“Goodrich”) is the Company’s Director of Corporate Media Relations since 2009. Defendant Goodrich is named as a defendant in the Securities Class Action.

30. ***Defendant Michael E. Sneed*** (“Sneed”) is the Company’s Chief Communications Officer since 2012; Executive Vice President of Global Corporate Affairs since January 2018; and a member of the Executive Committee since July 2018. Defendant Sneed was also Vice President of Global Corporate Affairs from 2012 to January 2018; Company Group Chairman, Vision Care Franchise from 2007 to 2012; Company Group Chairman, Consumer North America from 2004 to 2007; and held various positions of increasing responsibility across the global enterprise from 1986 to 2004. Defendant Sneed is named as a defendant in the Securities Class Action.

31. ***Defendant Joan Casalvieri*** (“Casalvieri”) was Director of Toxicology and Skincare at Johnson & Johnson Consumer Inc. (“JJCI”). Defendant Casalvieri is named as a defendant in the Securities Class Action.

32. ***Defendant Tara Glasgow*** (“Glasgow”) was JJCI’s Vice President of Baby R&D and Scientific Engagement from March 2014 to at least September 2016; and Vice President of Wound Closure and Repair at Ethicon, Inc., a subsidiary of the Company, from April 2017 to at least September 2018. Defendant Glasgow was also JJCI’s Senior Director of Oral Care Product Development and Innovation from October 2011 to March 2014 and held various positions of increasing responsibility at JJCI from 1995 to 2008. Defendant Glasgow is named as a defendant in the Securities Class Action.

33. Defendants Gorsky, Mulcahy, Prince, Perez, I. Davis, Williams, Washington, McClellan, S. Davis, and Beckerle shall be collectively referred to as the “Director Defendants.”

34. Defendants Mulcahy, Perez, I. Davis, and S. Davis shall be collectively referred to as the “Audit Committee Defendants.”

35. Defendants Gorsky, Goodrich, Sneed, Casalvieri, and Glasgow shall be collectively referred to as the “Officer Defendants.”

36. The Officer Defendants and Director Defendants are collectively referred to as the “Individual Defendants.”

**THE COMPANY’S CORPORATE GOVERNANCE  
AND CODE OF BUSINESS CONDUCT**

37. The Individual Defendants were required to comply with the Company’s Principles of Corporate Governance (the “Corporate Governance Principles”) and Code of Business Conduct (the “Code of Conduct”). The Individual Defendants were also required to comply with the Company’s Code of Business Conduct & Ethics for Members of the Board and Executive Officers (the “D&O Code of Conduct”). The Corporate Governance Principles state the following with respect to the responsibilities of the Board:

**Responsibilities of the Board.** All Directors are elected annually by the shareholders as their representatives in providing oversight of the operation of the Company. The Directors select, oversee and monitor the performance of the senior management team, which is charged with the day-to-day conduct of the Company's business. The fundamental responsibility of the Directors is to exercise their business judgment on matters of critical and long-term significance to the Company in furtherance of what they reasonably believe to be in the best interest of the Company, and therefore its shareholders.

38. The Company also claimed to conduct its business in accordance with applicable laws and regulations. To that effect, both the Code of Conduct and the D&O Code of Conduct required the Company’s officers and directors to comply with all laws, rules, and regulations, and the D&O Code of Conduct further required the Individual Defendants to “use all reasonable efforts to oversee compliance by employees, other Directors and other Executive Officers with all applicable laws,

rules and regulations.” The Code of Conduct provided the following with respect to legal and regulatory compliance:

We aspire to bring the highest standards and level of integrity to each of these business activities by:

- Complying with the laws, standards and regulations that apply to our products and processes (such as quality regulations and standards);
- Upholding ethical, scientific and clinical standards and complying with all laws and regulations in all research and development activities worldwide;
- Ensuring the safety of patients and volunteers who take part in clinical trials, protecting their confidentiality and complying with data protection laws;
- Complying with the laws and regulations that cover gaining marketing authorization to sell our products and interacting with regulators and other government officials;
- Adhering to the applicable manufacturing, packaging, distribution and export laws and regulations for our industry and in the countries where we do business;
- Following all laws and regulations regarding the promotion, marketing and sales of our products, including ensuring that what we say is truthful, not misleading, and is consistent with regulatory approvals for our products;
- Complying with all laws relating to product quality and safety, consistently monitoring the safety, quality and performance of our products and complying with all requirements for reporting adverse events and product quality complaints.

#### **DUTIES OF DEFENDANTS**

39. By reason of their positions as officers and/or directors of the Company, and because of their ability to control the business and corporate affairs of J&J, Defendants owed J&J and its investors the fiduciary obligations of trust, loyalty, and good faith. The obligations required Defendants to use their utmost abilities to control and manage J&J in an honest and lawful manner. Defendants were and are required to act in furtherance of the best interests of J&J and its investors.

40. Each director of the Company owes to J&J and its investors the fiduciary duty to exercise loyalty, good faith, and diligence in the administration of the affairs of the Company and in the use and preservation of its property and assets. In addition, as officers and/or directors of a publicly held company, Defendants had a duty to promptly disseminate accurate and truthful information with regard to the Company's operations, finances, and financial condition, as well as present and future business prospects, so that the market price of the Company's stock would be based on truthful and accurate information.

41. To discharge their duties, the officers and directors of J&J were required to exercise reasonable and prudent supervision over the management, policies, practices, and controls of the affairs of the Company. By virtue of such duties, the officers and directors of J&J were required to, among other things:

- (a) ensure that the Company complied with its legal obligations and requirements, including acting only within the scope of its legal authority and disseminating truthful and accurate statements to the SEC and the investing public;

- (b) conduct the affairs of the Company in an efficient, businesslike manner so as to make it possible to provide the highest quality performance of its business, to avoid wasting the Company's assets, and to maximize the value of the Company's stock;

- (c) remain informed as to how J&J conducted its operations, and, upon receipt of notice or information of imprudent or unsound conditions or practices, make reasonable inquiries in connection therewith, take steps to correct such conditions or practices, and make such disclosures as necessary to comply with federal and state securities laws;

- (d) ensure that the Company was operated in a diligent, honest, and prudent manner in compliance with all applicable federal, state and local laws, and rules and

regulations; and

(e) ensure that all decisions were the product of independent business judgment and not the result of outside influences or entrenchment motives.

42. Each defendant, by virtue of his position as a director and/or officer, owed to the Company and to its shareholders the fiduciary duties of loyalty, good faith, and the exercise of due care and diligence in the management and administration of the affairs of the Company, as well as in the use and preservation of its property and assets. The conduct of Defendants complained of herein involves a knowing and culpable violation of their obligations as directors and officers of J&J, the absence of good faith on their part, and a reckless disregard for their duties to the Company and its shareholders that the Defendants were aware, or should have been aware, posed a risk of serious injury to the Company.

## **COMPANY OVERVIEW**

### **Background**

43. The Company is a healthcare conglomerate with three core businesses: (i) Pharmaceutical, (ii) Medical Devices, and (iii) Consumer. Incorporated in 1887, the Company has grown exponentially over the years and considers itself to be “the world’s largest and most broadly based healthcare company.” The Company has credited its longevity and success to its “Credo.” First written over 75 years ago, shortly before the Company became a publicly traded company, “Our Credo” delineates the Company’s responsibilities to medical professionals, patients, and parents, as well as to its employees, communities, and shareholders. Engraved in an eight-foot sandstone slab weighing some 30,000 pounds that is proudly displayed in the lobby of the Company’s corporate headquarters, “Our Credo” is “ubiquitous” within the Company offices, appearing on desktops, bookshelves, walls, and hallways. It states in part that the Company’s “first

responsibility is to the doctors, nurses and patients, to mothers and fathers and all others who use our products and services. In meeting their needs everything we do must be of high quality.”

44. Along with the Company’s “Credo,” Johnson’s Baby Powder stands out as a symbol of the Company’s history and legacy. Recognized by the Company as a “flagship product” and “sacred cow” amongst its other offerings, Johnson’s Baby Powder is easily among “the top one or two products that people think of when they think of J&J.” Not only does each bottle prominently display the Company’s name, but according to the Company’s own internal documents, the fragrance of Johnson’s Baby Powder is “the most widely recognized fragrance in the United States.”<sup>1</sup>

45. The storied past of Johnson’s Baby Powder helps to further explain why the Company has considered the product to be its “sacred cow.”<sup>2</sup> “[T]he Company’s baby products business was born” when Johnson’s Baby Powder “made its debut in 1893, [and] went on the market in 1894.” A 2007 Company blog post explains:

Johnson’s Baby Powder was a success, and the Company began expanding its line of baby products to include creams, soaps, and more. Over time, Johnson’s Baby Powder, with its instantly recognizable scent, became *one of the most familiar and trusted products in the world*. [Emphasis added].

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<sup>1</sup> In an August 15, 2017 deposition, the Company corporate representative Hopkins admitted that Johnson’s Baby Powder was a flagship product and that “the baby powder is easily the top one or two products that people think of when they think of J&J.” He also admitted that “[i]n so far as Johnson’s Baby Powder was a sacred cow, an institution, a franchise, a flagship, a cornerstone of Johnson & Johnson’s business, it would be very, very bad for business if it ever came out that the baby powder or any of Johnson & Johnson’s talc products ever contained asbestos.”

<sup>2</sup> Merriam-Webster defines “sacred cow” as “one that is often unreasonably immune from criticism or opposition.” Further, Dictionary.com defines “sacred cow” as “an individual, organization, institution, etc., considered to be exempt from criticism or questioning.”

46. After World War I, the Company conducted “the largest ad campaign in its history” in order to promote the Company’s Baby Powder, which then became “trusted” by parents and associated “with the parent-infant bond”:

With the rapid growth of advertising in the Nineteen-teens after World War I, Johnson & Johnson advertised Baby Powder with the largest ad campaign in its history, with the result that the powder – and the Company’s other baby products – really took off and ***became trusted components of the way families across the world cared for their children.*** The products, by their very use, promoted close interaction between parents and their babies, and ***became associated in people’s minds with the parent-infant bond.*** [Emphasis added].

47. As a result, the Company has long been known as “the Baby Company,” even as it has acquired other brands and products:

Generations of families have used these products to care for their children, and consumer identification with them has been so strong that, ***despite the depth and breadth of its product lines, the Company has enjoyed a longstanding reputation as “the Baby Company.”*** [Emphasis added].

48. And as an internal memorandum from 1966 emphasized, “Baby Powder ***represents the cornerstone of [the Company’s] baby products franchise.***” [Emphasis added].

49. The Company has worked hard over the years to preserve the wholesome image of its flagship product. At least as far back as the 1970s, the Company told doctors and nurses how J&J’s Baby Powder was an “institution,” passed down in daily rituals from parent to child:

***JOHNSON’S Baby Powder is an institution.*** For many years it has been a familiar sight in millions of homes, used by millions of parents in caring for young children. Its sweet-smelling fragrance has become ***associated with freshness, comfort, and cleanliness.*** [Emphasis added].

50. Exploiting these memories and associations, the Company has historically urged people of all ages to “[t]hink of us as a lifetime friend of the family” and to continue to use Johnson’s baby products after childhood – promising that “[a]ll those good comfortable feelings you felt when you were young stay with you as an adult.” Even today, the Company regularly reminds



the public of the legacy and supposed benefits of Johnson's Baby Powder. For example, on a 2016 webpage entitled "The Facts on talcum powder safety," the Company boasted:

***If you've ever cared for a baby, you've probably had JOHNSON'S Baby Powder in your home.*** Baby powder made from cosmetic talc is one of the JOHNSON'S brand's oldest products and a ***longtime part of baby care rituals.*** It is hypoallergenic, helps eliminate friction and is clinically proven to be gentle and mild for your baby's skin. ***The clean, classic scent is comforting and familiar for parents and children alike.*** [Emphasis added].

51. Despite all of the Company-promoted associations with sentimental rituals and memories, Johnson's Baby Powder is essentially just ground up minerals with a bit of "fragrance." The principle ingredient of the Company's Baby Powder and talcum powder products is talc, a naturally occurring mineral that is first mined and then ground into powder form.<sup>3</sup>

52. Talc can be naturally contaminated with asbestos, as the two can develop together within the same ore bodies. Asbestos is the commercial term used to describe minerals developing naturally as bundles of long, thin fibers that are flexible and easily separable, rather than as solid rock. These "asbestiform" minerals include chrysotile, tremolite asbestos, actinolite asbestos, anthophyllite asbestos, amosite, and crocidolite. Asbestos fibers can cause fatal cancers and wreak absolute havoc on human tissue, even when present in such small quantities that they are invisible without sophisticated detection methods and equipment. The U.S. federal government has made

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<sup>3</sup> The Company has sold two principal talcum powder products over the years: Johnson's Baby Powder and Shower to Shower. Valeant Pharmaceuticals International Inc. bought Shower to Shower from the Company in 2012. From the mid-1960s until 1989, the Company's talc was largely supplied by its own subsidiary, Windsor Minerals, and came from its Vermont mining operation. As a 1966 the Company memorandum illustrates, the Company historically had "a large investment in a talc mine." Currently, Johnson's Baby Powder sold in the U.S. contains talc that is imported from mines in China and supplied by Imerys.

clear that *there is no known safe level of exposure to asbestos*. Even trace amounts are considered dangerous.<sup>4</sup>

**THE EARLY YEARS – AMIDST HEALTH CONCERNS  
REGARDING ASBESTOS AND TALC, THE COMPANY  
BEGINS ITS DECADES-LONG SCHEME TO CONCEAL THE TRUTH**

53. Concerns about asbestos and its potential effects on human health grew during the 1960s, and as a result of this heightened awareness, questions about the safety of talc-based products and their potential asbestos contamination began to be raised in earnest in the early 1970s. Despite being repeatedly informed of the presence of asbestos in the Company’s talc and talcum powder, the Company lied to the public, influenced regulators, and purposely avoided testing methods that could detect the trace amounts of asbestos that the Company knew were present.

**THE COMPANY RECOGNIZES INTERNALLY THAT ITS TALC IS  
CONTAMINATED AND THAT IT COULD LEAD TO  
A PUBLIC “FUROR” AND LITIGATION**

54. By 1969, the Company had already recognized that asbestos contamination posed a direct threat to its iconic brand and raised the specter of litigation exposure. In a 1969 memorandum, Dr. T.M. Thompson (“Thompson”) of the Company noted the general concerns that had previously been raised about the safety of Johnson’s Baby Powder, including by Robert Wood “General” Johnson II (“General Johnson”), son of the Company’s co-founder Robert Wood Johnson.<sup>5</sup>

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<sup>4</sup> Tremolite, actinolite, and anthophyllite minerals can also develop naturally as larger rocks, *i.e.*, “non-asbestiform.” However, these rock formations can be broken down by industrial processes such as grinding, leading to “cleavage fragments.” These fragments can have substantially similar characteristics as naturally occurring asbestos, with the potential to pose the same health risks as “asbestiform” minerals. According to Richard Zazenski (“Zazenski”), long-time employee of the Company’s talc supplier, “if a deposit contains ‘non-asbestiform’ tremolite, there is also asbestiform tremolite naturally present as well.” Where there is tremolite there is asbestos present.

<sup>5</sup> General Johnson, who served as chairman of the Company from 1932-1963, has been credited with turning the Company into the largest health-care company in the world. He also wrote the Company’s celebrated Credo.

Thompson indicated that General Johnson and numerous pediatricians had “express[ed] concern” about potential “adverse effects on the lungs of babies or mothers.” Thompson then went on to admit that the Company’s talc contained “unavoidable trace amounts” of tremolite, and that these structures could penetrate deep inside the lungs:

[W]e have occasionally received inquiries from various individuals, including General Johnson and several pediatricians, *expressing concern over the possibility of the adverse effects on the lungs of babies or mothers who might inhale any substantial amounts of our talc formulations*. In the past, we have replied to the effect that since our talc is essentially all of the platelet-type of crystalline structure, and is of a size which would not be likely to enter the pulmonary alveoli, we would not regard the usage of our powders as presenting any hazard. Obviously, if we do include Tremolite in more than *unavoidable trace amounts*, this sort of negation of such inquiries could no longer pertain. [Emphasis added].

55. Thompson also acknowledged to other Company personnel, including Ashton, that “if it became known that [its] talc formulations contained any significant amount of Tremolite,” the Company could face “such a furor” that it could be “more or less compelled to remove [tremolite] from the formulation”:

Some years ago, we were faced with a more or less serious problem resulting from what we consider to have been an unjust accusation of danger due to the presence of a small amount of boric acid in our talc. This *created such a furor* that we were more or less compelled to remove boric acid from the formulation. It is conceivable that *a similar situation might eventually arise if it became known that our talc formulations contained any significant amount of Tremolite*. [Emphasis added].

56. Thompson further warned that the Company could face litigation over tremolite in its talc, and he suggested that the Company’s law department be involved:

Since the usage of these products is so widespread, and the existence of pulmonary disease is increasing, it is not inconceivable that *we could become involved in litigation* in which pulmonary fibrosis or other changes might be rightfully or wrongfully attributed to inhalation of our powder formulations. It might be that *someone in the Law Department should be consulted with regard to the defensibility of our position in the event that such a situation could ever arise*. [Emphasis added].

**THE COMPAMNY TELLS THE PUBLIC THAT ITS BABY POWDER CONTAINS NO ASBESTOS, BUT NUMEROUS INTERNAL DOCUMENTS AND THE COMPANY'S OWN EFFORTS TO REMOVE THE ASBESTOS SHOW OTHERWISE**

57. In June 1971, the Company attempted to put concerns about its talc to rest by issuing a statement to the *New York Daily News* and *New York Post*:

Johnson & Johnson takes great care to assure the purity of its products, even to the extent of mining and processing our own talc for use in baby powder. Our fifty years of research knowledge in this area indicates that ***there is no asbestos contained in the powder manufactured by Johnson & Johnson.*** [Emphasis added].

58. Contrary to the Company's public assurance, however, the Company already knew that its talc contained asbestos. Indeed, a little over a month after the Company's June 1971 press release assuring based on "fifty years of research knowledge" that the powder contained "no asbestos," a July 1971 memorandum by the Company's Wilson Nashed noted that "[t]he talc used in JOHNSON'S Baby Powder" came from a Vermont mine containing "trace amounts of fibrous minerals (tremolite/actinolite)." While the talc went through a "washing process," "three independent consulting laboratories" showed that the resulting talc still had "traces of fibrous minerals":

The talc used in JOHNSON'S Baby Powder is obtained from a selected mine in Vermont where the ore consists mainly of platy talc with only ***trace amounts of fibrous minerals (tremolite/actinolite).*** It is free of chrysotile fibers which may be called "pure asbestos" by the layman.

The ore undergoes a careful purifying process which includes a 36-step washing process to maximize its content of high lubricity platy talc and to remove or substantially reduce any traces of fibrous minerals which may be present in the unrefined ore. ***The resulting talc has been shown by three independent consulting laboratories[] to contain negligible traces of fibrous minerals and no chrysotile fibers.*** [Emphasis added].

59. Then, in 1972, University of Minnesota professor Thomas E. Hutchinson ("Professor Hutchinson") tested talcum powder samples received from the Company and an outside laboratory, and he found chrysotile in a Shower to Shower sample – or what he described as "incontrovertible

asbestos” in a lab note. While the Company submitted testing results to the FDA and claimed that they “clearly show[ed]” “no chrysotile asbestos,” the Company withheld the findings of Professor Hutchinson.

60. In August 1972, the Company was informed by Dr. Weissler, Director of the Division of Cosmetics at the FDA, that a sample of the Company’s Shower to Shower talcum powder product had been sent to Sperry Rand, an outside laboratory facility, and that the report “was that *asbestos fibers could be detected*.” The Company attempted to discredit the results, asking Dr. Weissler about the facility’s experience and potential for lab contamination, but internally *admitted the potential presence of tremolite fibers in its products*:

The report from Sperry Rand was that *asbestos fibers could be detected* in the sample. Dr. Weissler said that he has in front of him photographs of 6 fields at 12,000X magnification showing fibers with length to width ratios of 10-to-1 to 50-to-1 . . . . I asked Dr. Weissler if the Sperry Rand facility handles minerals.

He said yes, they do a lot of work with chrysotile. I asked him, “Have they reported to you the normal background contamination in their samples. As you recall, this was the problem in Mt. Sinai’s laboratories.” He said no; however, he feels that the man who did the work is conservative and would not have reported chrysotile unless he was sure. *I asked him if he has assured himself that the fibers were not tremolite which could be present in trace amounts. He said the fibers are characteristic of chrysotile and not tremolite.* [Emphasis added].

61. Other internal documents from the 1970s also demonstrate the Company’s awareness of its asbestos contamination problem. For example, a February 1973 Company memorandum illustrates that the Company consultant Fred Pooley was working on a process to remove tremolite from talc, which Tom Shelley (“Shelley”), Director of the Company’s Central Research Laboratories, considered to be potentially a “valuable patent” for the Company. But after a little over a month of contemplation, Shelley determined that it could be in the Company’s best interest to *“keep the whole thing confidential” rather than “let the whole world know”* that the Company was trying to remove asbestos from its talc:

[W]e will want to carefully consider the Pooley patents re asbestos in talc. It's quite possible that we may wish to keep the whole thing confidential rather than allow it to be published in patent form and thus let the whole world know.

62. Then, in August 1973, the Company was informed that the Dutch Consumer Organization had found asbestos in Johnson's Baby Powder. The Company asked the organization to not make its findings public. A December 13, 1973 letter from the Company's operation in the Netherlands, with "*asbestos in baby powder*" as the subject, stated:

During the month August the Dutch Consumer Organization has informed us that *they have determined asbestos in JOHNSON's Baby Powder*.

According to their first test the content was 1.59%. On our request they have tested another sample and the result of this second test was 0.3%.

During the period August/November we have had continuous contacts with them and we have supplied them with all the data and comments we received from Johnson & Johnson U.S.A. and Johnson & Johnson U.K.

*We also asked them clearly not to make any publications about asbestos in baby powder*, before we agreed with their findings.

Because *they did not accept our arguments against their method of testing* we have proposed a discussion between our experts and theirs.

We have tried this several times. [Emphasis added].

63. By 1974, the Company was also authorizing asbestos-destruction experiments in Colorado. An April 1974 memorandum containing notes on a visit with the Colorado School of Mines details the Company's authorization of experiments to establish the destruction of tremolite and chrysotile in the presence of Vermont talc, and to "[d]etermine whether or not fibrous structure is retained or destroyed in above." Once again, the Company was considering turning a profit on the asbestos contamination, as the experiments were "to be run on [the] low key," "up to [the] point where we can file patent protection."

**THE COMPANY SETS OUT TO INFLUENCE REGULATORS AND PURPOSELY AVOIDS "ESSENTIAL" ASBESTOS TESTING METHODS**

64. Knowing that there were “unavoidable trace amounts” of tremolite (asbestos) in its talc, the Company also knew that it would likely fail in finding a way to completely eliminate asbestos from its talc. This made it even more critical that the Company prevent the asbestos contamination from becoming public knowledge. The Company embarked on a campaign to undermine scrutiny by public health officials and doctors, branded internally in November 1972 as “Antagonistic Personalities.” These individuals included the Director of the Environmental Protection Agency (“EPA”) of New York City, an FDA official “who [was] seeking recognition within the FDA” and “seem[ed] particularly anxious to condemn talc,” and a doctor at the Mt. Sinai Hospital and others in his department with “the same mental attitude,” including Dr. Arthur Langer (“Langer”), who had told the Company of his finding of asbestos in the Company’s “baby talc” the year prior in a November 1971 letter.<sup>6</sup>

65. In defending its flagship product, the Company paid particular attention to the FDA and directly sought to influence it. For example, in October 1973, the Company analyzed a proposed FDA regulation regarding the method for determining the presence of asbestos in food and drugs, determining that while the method of analysis would “show that our talc is acceptable,” “if they change the method, we may have problems.” The Company then contributed to a December 1973 letter from the CTFA to the FDA arguing that it was “premature for FDA to impose its proposed optical method and place a limit on asbestos in talc for food use.”

66. Meanwhile, the Company purposely avoided essential testing methods. As the Company’s own consultant, Colorado School of Mines, confirmed in December 1973, looking for

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<sup>6</sup> *Reuters* would report in December 2018 that “Langer said he told J&J lawyers who visited him last year that he stood by all of his findings,” which included “trace amounts of chrysotile asbestos” in the Company’s talc.

trace amounts of asbestos in talc is like trying to find a “needle in a haystack,” and so requires looking at an increasing amount of talc. In order to do this, a method of preconcentrating any asbestos content is “essential”:

As the impurity level becomes very low ( $\ll 1\%$ ), it is necessary to examine increasingly larger amounts of sample in order to detect the impurity. As a result of the requirement to detect the proverbial “*needle in a haystack*,” we have evolved a procedure which preconcentrates the impurities prior to examination.

\* \* \*

The objective of this work was to develop a procedure to screen talc for the presence of chrysotile and tremolite-actinolite asbestos minerals. Based on past experiences with detecting and identifying minerals when present at low levels, *a concentration of the phases to be detected was considered essential to the success of any suggested procedure*. Once concentrated the impurities could be detected by conventional methods of examination. [Emphasis added].

67. A May 1973, the Company report entitled “Proposed Specs for Analyzing Talc for Asbestos” illustrates that the Company knew that asbestos was in its talc and that concentration methods would allow laboratories to find it, making such methods “too sensitive” for the Company’s taste:

England is considering method of preconcentrating the asbestos so as to be able to analyze by X-ray. *They find no “asbestos” by doing this with Italian talc. They find (Pooley) 0.05% of a tremolite-type in Vermont.*

\* \* \*

Preconcentration of Asbestos followed by X-Ray Diffraction Analysis (Pooley Method)

Dr. Pooley has developed two techniques for preconcentration of chrysotile and tremolite in talc followed by X-ray diffraction analysis. . . . The second technique developed also by Dr. Pooley involves preconcentration of tremolite in talc (different procedure) followed by X-ray diffraction analysis. This technique has not been written up yet, but *evidently when applied to Vermont talc, 0.05% of tremolite-type is found. The limitation of this method is that it may be too sensitive*. [Emphasis added].



68. The Company's purposeful avoidance of sophisticated testing methods is further evidenced in a February 1975 internal Company memo to its British operation, attaching "minutes of the CTFA task force on methodology for the detection of asbestos in talc" and stating that it was looking at these methods "very quietly" "to avoid promotion of this approach":

We are presently practicing and evaluating the Pooley flotation method so we are not in the position to recommend it at this time. Besides, *we feel that a detectability limit with our two present methods of 0.5% to 1% is reasonable . . . .* Our major problem with the Pooley procedure is that since one can continually recycle the tailings (concentrate) given enough time, it is possible to arrive at levels of detectability of asbestos in talc in the ppm range – at what stage of recycling do you stop? *We really want to exclude concentration techniques in any proposed analytical procedure and are really looking at this method very quietly* so that we will be informed and up-to-date with this area of technology. *We want to avoid promotion of this approach.* [Emphasis added].

69. A November 1976, the Company memorandum from Ashton declared that separation and concentration techniques were "disturbing," as their implementation would make the talc industry "hard pressed in supporting purity claims" and could "open up new problem areas with asbestos and talc minerals":

Attached is a copy of *a disturbing proposal request* which the FDA has currently made available to qualified bidders. The scope of the work is the Separation of Asbestos in Foods, Drugs and Talc for Identification and Determination.

*I find this proposal more disturbing* than other proposals up to now because it aims at separation and isolation of asbestos from a wide scope of products and animal tissues. Up to now, our main problems have had to do with identification, whereas, now it looks like *the FDA is getting into separation and isolation methodology which will mean concentration procedures. As I have pointed out many times, there are many talcs on all markets which will be hard pressed in supporting purity claims, when ultra sophisticated assay separation and isolation techniques are applied. Chances are that this FDA proposal will open up new problem areas with asbestos and talc minerals.* [Emphasis added].

70. To this day, the Company has not adopted a concentration method for testing its talc despite the Company's knowledge that this would allow detection of asbestos in its talc and talcum powders when present in trace amounts.

**THE COMPANY MONITORS AND DEFENDS  
AGAINST SCIENCE AND REGULATIONS**

71. During the 1970s, while the Company worked to avoid the use of sophisticated and "essential" testing methods on its products, the Company also set out to defend its Baby Powder's image by undermining scientific studies and research. An internal memorandum from March 1975 ("March 1975 memorandum") illustrates that the Company's initial approach "with respect to sponsorship of talc safety studies" had been defensive, with the Company "initiat[ing] studies only as dictated by confrontation." The March 1975 memorandum recognized that this approach "has allowed us to neutralize or hold in check data already generated by investigators who question the safety of talc." Much like an ostrich with its head in the sand, the Company's "principal advantage" with this approach was that it "minimize[d] the risk" of the Company itself inadvertently generating "scientific data which may be politically or scientifically embarrassing." Activities proposed under this approach included (i) involvement in a study "directed towards demonstrating that pulmonary function is not impaired by exposure to cosmetic grade talc," and (ii) funding "Johnson & Johnson's monitoring of the NIOSH Harvard Study of Vermont Talc Workers" and the Company's "analytical and statistical verification of the data to be gathered."

72. But the March 1975 memorandum also acknowledged the weaknesses of this defensive strategy:

[T]his approach leaves the talc franchise and the company image open to repeated erosion by prior public disclosure of suspected hazards and adversary politicking. Also, there exists a danger that the latent period for generating J&J data might be too great for the data to be effective.

73. Thus, the March 1975 memorandum proposed “a more anticipative approach” that had been discussed at the Talc Advisory Group:

We would *carry out other reasonable safety studies to continue our contradiction of generated negative data and to anticipate questions on safety* which will probably be raised. This philosophy offers *maximal leverage for defending the product* . . . . [Emphasis added].

74. An August 1977 J&J “Status Report” on the “Defense of Talc Safety” provided an update on “*the talc safety defense program*” that J&J had been conducting. Noting that cosmetic talcs had not suffered “disruptive influences” in the past two months, the Company recognized the effectiveness of “the various Company sponsored studies [that had] been disseminated effectively” to the United Kingdom and U.S. scientific and medical communities:

The past two months have seen no disruptive influences and to the contrary, the *cosmetic talcs have enjoyed confirming reassurance* from several independent authoritative sources that they are assessed to be free of hazard for normal consumer use.

*We attribute this growing opinion* to the fact that (1) the existence of CTFA’s self-regulating cosmetic grade talc specification has become common knowledge and that (2) favorable data from the various J & J sponsored studies have been disseminated effectively to the scientific and medical communities in the U.K. and U.S. [Emphasis added].

75. An internal Company report regarding the Company’s “Special Talc Study,” for the period of December 1977 – January 1978, illustrates the Company’s continued efforts of creating research and data that could be used to protect “the safety image” of Johnson’s Baby Powder:

OBJECTIVE:

*To monitor and defend against consumerist, scientific and regulatory attitudes/trends* which could impact adversely on the safety image and marketability of cosmetic talcs.

*To generate or provide necessary data to support and reinforce the safety of our baby powder.* [Emphasis added].

76. The “Special Talc Study” report also explains how the Company *was again informed that its Baby Powder and talc were contaminated with asbestos*. “A visit was made” to a facility to preview “a new instrument” that “detects and counts airborne fibers in the presence of high concentrations of non-fibrous particles.” Johnson’s Baby Powder and the Company’s talc were tested with this device, and the “results indicat[ed] our talc and product are well below the current 2 fibers/cc permitted for asbestos,” as “JBP” (Johnson’s Baby Powder) had come back with 0.08 fibers/cc and J&J’s V-66 Talc had come back with 0.28 fibers/cc.

**1980S TO 2000S – THE COMPANY FACES A NEW BATTLEFRONT IN THE WAR TO DEFEND ITS FLAGSHIP PRODUCT: THE ASSOCIATION BETWEEN THE USE OF TALCUM POWDER AND OVARIAN CANCER**

77. Beginning in the 1980s, the Company faced a growing body of research finding evidence of an association between talcum powder usage for personal hygiene and ovarian cancer. Notably, because the Company had convinced the world that the Company’s talcum powders were asbestos-free, the public health research focused on the question of whether there was a connection between ovarian cancer and the talc itself.

78. Knowing that public health researchers were bringing increased attention to talc and that this could threaten the Company’s concealment of its talc’s asbestos contamination, the Company sold its Hammondsville mine, which had served as *the primary source of talc for J&J’s flagship product since 1966, to Cyprus in 1989*. The Company did this shortly after *destroying most of the records* of the Hammondsville mining operation. A November 23, 1993 J&J memorandum explains:

The specifics of the mining operation at Hammondsville are uncertain, as most of the pre-Luzenac records were destroyed by the mine management staff just prior to the J&J divestiture and the Cyprus purchase. However, several former Hammondsville miners are still employed at the Ham mine, and they provided us with useful information as to the nature of the underground works.

79. Meanwhile, a March 1992 internal memorandum at the Company's talc supplier illustrates that it was common knowledge at the Vermont mining operation that asbestiform minerals were present. Indeed, the memorandum illustrates that there was "certainly visible tremolite and actinolite in specific zones," and that "Cyprus staff report past tremolite from the Hammondsville and Clifton deposits":

Vermont talcs are derived from altered serpentinite – *a natural host for asbestiform minerals. There is certainly visible tremolite and actinolite in specific zones of the Vermont deposits* – fibrous tremolite was identified by the writer in exposures and cores at the East Argonaut and Black Bear mines. *Cyprus staff report past tremolite from the Hammondsville and Clifton deposits.* [Emphasis added].

80. As researchers examined talc as a potential carcinogen, government interest in talc returned and NIOSH nominated talc for study by the NTP. In 1993, the NTP reported finding evidence of talc's "carcinogenic activity" in an inhalation study performed with rodents. With public health researchers and regulators moving closer to discovering the Company's massive cover-up, the Company took aggressive action to conceal the asbestos contamination of its talc and talcum powders.

**THROUGH FALSEHOODS AND MANIPULATION, THE COMPANY AND ITS  
INDUSTRY COHORTS SUCCESSFULLY PREVENT TALC FROM  
BEING LISTED IN THE "10TH REPORT ON CARCINOGENS"**

81. As government interest in talc grew, the Company set out to stay "at the forefront of cosmetic talc" and have "worldwide oversight on talc issues." An August 1993 internal memorandum from Donald Jones to John Hopkins stated:

John, I'm sure you've heard that FDA asked ISRTP to organize a talc safety symposium. The request is a follow-up to both the 1992 NTP findings regarding talc and the 1992 Harlow paper resurfacing the ovarian cancer connection to cosmetic talc use first proposed by Cramer.

\* \* \*

[A]s part of a strategy to *keep J&J at the forefront of cosmetic talc, and to insure that we have worldwide oversight on talc issues*, Mary AnnCook and I are organizing a Worldwide Talc Steering Committee. [Emphasis added].

82. At the same time, the Company also continued to receive dire warnings regarding its talcum powder's association with ovarian cancer. For example, in a November 10, 1994 letter from the Cancer Prevention Coalition, the Company's CEO at the time, Ralph Larson, was alerted to the scientific evidence of an association between talcum powder and ovarian cancer:

Dear Mr. Larson,

A wide range of scientific studies dating back to the 1960s shows conclusively that the frequent use of talcum powder in the genital area poses a serious risk of ovarian cancer.

Dr. Bernard Harlow, a leading ovarian cancer researcher from Harvard Medical School, published a comprehensive study in 1992 of the link between talc and ovarian cancer. The study found a threefold increase of ovarian cancer in women who used talc in the genital area as a daily habit.

\* \* \*

Furthermore, the U.S. National Toxicology Program has recently confirmed that talc is carcinogenic.

83. By September 1997, the Company was participating in industry representations that its own consultant described as "inept," "inaccurate," and "outright false," all in an effort to conceal the asbestos contamination of its flagship product. In a letter from Alfred Wehner ("Wehner") to the Company's Manager of Preclinical Toxicology Michael Chudkowski ("Chudkowski"), the Company was warned of the troubling posture it was taking along with its industry allies:

Several investigators have independently reported talc particles in ovarian tissue. Simply citing the Battelle study and stating that it "demonstrated that talc does not translate (sic!) through the cervix to the uterine cavity and beyond does not address the problem . . . . All in all, in my opinion an inept response.

The problem with the response statement dated July 8, 1992, is more serious. The last sentence in the second paragraph states: "Finally, human studies on talc and cancer in industrial settings have shown that industrial exposure to talc, both by skin

contact and inhalation, even at levels thousands of times higher than lifetime consumer exposure, presents no significant risk.” ***This statement is outright false.***

\* \* \*

The response statement dated November 17, 1994, is just as bad. The second sentence in the third paragraph reads: “The workshop concluded that, although some of these studies suggest a weak association might exist, when taken together the results of the studies are insufficient to demonstrate any real association.” This statement is also inaccurate, to phrase it euphemistically. At that time there had been about 9 studies (more by now) published in the open literature that did show a statistically significant association between hygienic talc use and ovarian cancer. ***Anybody who denies this risks that the talc industry will be perceived by the public like it perceives the cigarette industry: denying the obvious in the face of all evidence to the contrary.*** [Emphasis added].

84. At the same time that the Company and its allies were vehemently denying the link between talc and ovarian cancer in order to avoid the public discovery of the asbestos contamination, the Company was again informed that its talcum powder was contaminated with asbestos. In an April 1998 letter to Mehaffy & Weber, lawyers for JJCI, Dr. Alice Blount (“Blount”) stated that the Company’s talc “contains trace amounts of asbestos”:

Although my papers report an improved method for analysis, the determinations for the sample labeled I (Johnson & Johnson’s Vermont talc) have been done by the traditional methods as well . . . . ***As I told you, I believe that Johnson & Johnson’s Vermont talc contains trace amounts of asbestos*** which are well below those specified by OSHA. [Emphasis added].

85. Blount identified the Company’s Vermont talc as the Sample I from her 1991 paper, which detailed her findings of asbestos “[n]eedles and fibers” in that sample and that the aspect ratio distribution for Sample I tracked that of tremolite asbestos.

86. By October 2000, the first two groups of the NTP’s review process had voted 13-2 in favor of listing talc in the 10th RoC. This raised the stakes considerably for the Company, bringing researchers and regulators one step closer to discovering the Company’s longstanding fraud. In response, the Company and its talc supplier worked to undermine the NTP, and by November 27,

2000, the Company's talc supplier had found and proudly shared with the Company the "Winning Hand" in how to defeat the NTP. In an email to the Company's Chudkowski attaching comments from lobbying group CRE, Luzenac's Zazenski boasted that the companies now had a way to get talc out of "this NTP nonsense":

I'll let you guys read this for now . . . but it's for your eye's only until we finalize it. It's the winning hand in getting talc without asbestos dismissed from this NTP nonsense.

For now, I'll graciously accept 100% of the credit 1) finding CRE, 2) convincing them to get involved, 3) *developing the Fatal-Flaw Strategy*[,] 4) *single-handedly saving the talc business from certain ruin*.

All in a day's work. All contributions to the RJZ vacation and retirement fund will be accepted. [Emphasis added].

87. As it turns out, the "fatal flaw" was rather simple. Because many of the epidemiology studies linking genital talc use to ovarian cancer did not distinguish talcum powders produced after 1976 (which was purportedly required to be "asbestos free") from those produced before 1976, it was supposedly impossible to know whether the results were because of asbestos in the talc or because of the talc itself. As Zazenski would explain:

*The primary reason non-asbestiform talc was able to survive* the third NTP meeting in December and not be recommended for listing *was the introduction of doubt* concerning the characterization of talc utilized in dusting powders cited in the epidemiology studies. All but one of the sixteen ovarian cancer studies would have involved the use of cosmetic talc and baby powder produced prior to 1976, the year that CTFA introduced cosmetic talc specifications requiring no asbestos.

Two days after the draft CRE comments were shared with J&J, the CRE submitted its letter to the NTP, claiming that CRE "is not affiliated with any particular industry, company, or other entity." [Emphasis added].

88. The "fatal flaw" strategy was successful, as the NTP deferred consideration of listing talc because "there ha[d] been considerable confusion over the mineral nature and consequences of exposure to talc, both containing asbestiform fibers and not containing asbestiform fibers." In



response to an e-mail from Mann referencing Zazenski's "history with J&J on defending talc," Zazenski would provide further details:

[D]uring the 10th RoC review, the Center for Regulatory Effectiveness (Washington, D.C.) took an active role in ensuring that NTP was conducting a proper review of talc. ***CRE was instrumental in helping divert an almost guaranteed listing for talc into a "deferral. . . ."*** I might point out that in the 10th RoC review, RG1 and RG2 voted 13-2 to list talc (not containing asbestos) as a carcinogen. Up until then, every substance nominated for listing by both RG1 and RG2 went on to be listed. [Emphasis added].

89. As the Company's talc supplier also summarized the events internally, admitting that, "[w]e (the talc industry) dodged a bullet . . . based entirely on the confusion over the definition issue." Of course, the cruel irony that the Company and Luzenac failed to mention to the NTP or the public health researchers was that the "fatal flaw" was illusory, as the Company's talc and Baby Powder continued to be contaminated with asbestos.

90. But while the Company was able to keep talc off of the NTP's 10th RoC, fears of its fraudulent scheme being revealed lingered at the Company as it faced the threat of the NTP post-deferral, as well as a new potential foe – the WHO's International Agency for Research on Cancer, or IARC, which "[u]nlike NTP," was "answerable to no one politically." As Zazenski warned Ashton on March 26, 2002:

We've been successful thus far in fending off the NTP classification of talc as being a potential human carcinogen. But we must also ***keep an eye out for IARC. . . .*** IARC reviews are not a public debate. Unlike NTP, ***IARC is answerable to no one politically*** (they are headquartered in Lyon, France of all places). As part of the World Health Organization, ***they act very independently to protect the citizens of this planet from 'preventable' diseases. . . .*** You might want to counsel your management on this potential (and not to be too complacent about the status of talc). [Emphasis added].

## **FALSE AND MISLEADING STATEMENTS**

### **February 2013 False and Misleading Statements**

91. On February 22, 2013, Defendants caused the Company to file its Form 10-K with the SEC for the fiscal year ended December 30, 2012 (“2012 10-K”). According to Defendants, the Company “remain[ed]” committed” to “delivering high quality” and “improving existing products”:

#### ***Research and Development***

Research activities represent a significant part of the Company’s businesses. Research and development expenditures relate to the processes of discovering, testing and developing new products, ***improving existing products***, as well as demonstrating product efficacy and regulatory compliance prior to launch. ***The Company remains committed to investing in research and development with the aim of delivering high quality and innovative products.*** [Emphasis added].

92. Exhibit 13 to the 2012 10-K disclosed that some of the Company’s subsidiaries were involved in product liability litigation, but also represented that the warnings and instructions accompanying their products were adequate:

Certain subsidiaries of Johnson & Johnson are involved in numerous product liability cases. The damages claimed are substantial, and while these subsidiaries are confident of the adequacy of the warnings and instructions for use that accompany the products at issue, it is not feasible to predict the ultimate outcome of litigation. The Company has established product liability accruals in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. Changes to the accruals may be required in the future as additional information becomes available.

93. The Company’s statements above were false and misleading when made. While Defendants boasted of “improving existing products,” being “committed to investing in research and development with the aim of delivering high quality . . . products,” and having “adequate” warnings, they omitted that (i) asbestos had repeatedly been found in the Company’s talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, and (iii) the Company never adopted concentration methods that could detect the asbestos.

### April 2013 False and Misleading Statements

94. On April 25, 2013, *Forbes* reported on comments made by the Company's VP of global corporate affairs, Michael Sneed, at the Company's annual shareholder meeting:

"One of the things that we wanted to be sure to do is move to ***really get past some of the challenges we've had as a business,***" said Michael Sneed, VP of global corporate affairs. "***We've made great strides in that and we want to make sure we have a full conversation about who J&J is.*** We're not perfect but we want people to understand that ***when we do make mistakes, we own up to those mistakes and we want people to understand the values that are behind J&J.***"

J&J ranked No. 6 of America's 150 most reputable companies this year, dropping from No. 3 last year, according to The Reputation Institute.

"We certainly are not oblivious to the rankings," Sneed said. "The reputation of J&J is very important to us. We take it very seriously. We have a lot of data that we look at, both externally and internally," he said. "I wouldn't say there was any one thing that precipitated [the campaign], and we certainly don't do these things just for rankings. Reputation is something that's born out of actions. The reputation is a reflection of people's perspective on the actions that we do take."

The corporate campaign is the first global one, will continue indefinitely and will cost an estimated \$20 million to \$30 million for the remainder of the year.

It comes at a time when many businesses such as Nestle, Unilever UN +0% and Procter & Gamble PG +1.22% recognize the value of corporate branding in an increasingly transparent and accessible world driven by social media. "***We've really embraced transparency*** because we think we've got a great story to tell," Sneed said. "It has made us even more committed to making sure that we're part of the conversation wherever that conversation happens. Clearly, more of that conversation happens online and in the digital space. We love that things happen in real time. We get jazzed at being part of that," he said, adding that employees, particularly the younger ones, are excited by the company's involvement in social media, and "have become ambassadors for the brand."

Sneed also pointed out that J&J has a history of doing corporate campaigns – for example, the Campaign for Nursing's Future, which has been running for 10 years.

"As we were thinking about what else we wanted to do, we thought it was important to reconnect with customers, healthcare professionals, and reconnect them to J&J and ***really [help them] understand the values behind J&J.*** The campaign is about celebrating the people who do the work of caring for others and in a selfless manner."

The central theme of the new ads, the first from TBWA LA, is love – “*an expression of what people do when they care unconditionally for others*,” Sneed said. “That comes out of the history of J&J.” [Emphasis added].

95. Defendants’ statements above that the Company had “‘really embraced transparency’” and was trying to “‘have a full conversation about who the Company is’” to help customers, healthcare professionals, and others “‘understand the values behind the Company,’” that the Company had a history of and was driven by “‘car[ing] unconditionally for others’” and that it had “‘own[ed] up to [its] mistakes,’” and that the Company made “‘great strides’” in “‘really get[ting] past’” the quality issues the Company faced, were false and misleading. In truth, Defendants were continuing the longstanding campaign to conceal the dangers inherent in the Company’s talcum powders. Indeed, Defendants failed to disclose that (i) asbestos had repeatedly been found in the Company’s talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, and (iv) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company’s flagship product and reputation.

#### **May 2013 False and Misleading Statements**

96. On May 3, 2013, Defendants caused the Company to file its Form 10-Q with the SEC for the first quarter of 2013 (“1Q13 10-Q”). According to Defendants, the Company “remain[ed] committed” to “delivering high quality” and “improving existing products”:

#### **Research and Development Expense**

Research and development activities represent a significant part of the Company’s business. These expenditures relate to the processes of discovering, testing and developing new products, *improving existing products*, as well as ensuring product efficacy and regulatory compliance prior to launch. *The Company remains committed to investing in research and development with the aim of delivering high quality and innovative products.* [Emphasis added].

97. The Company's 1Q13 10-Q disclosed that some of the Company's subsidiaries were involved in product liability litigation, but also represented that the warnings and instructions accompanying their products were adequate:

Certain subsidiaries of Johnson & Johnson are involved in numerous product liability cases. The damages claimed are substantial, and while *these subsidiaries are confident of the adequacy of the warnings and instructions for use that accompany the products at issue*, it is not feasible to predict the ultimate outcome of litigation. The Company has established product liability accruals in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. Changes to the accruals may be required in the future as additional information becomes available. [Emphasis added].

98. Defendants' statements above were false and misleading. While Defendants boasted of "improving existing products," being "committed to investing in research and development with the aim of delivering high quality . . . products," and having "adequate" warnings, they omitted that (i) asbestos had repeatedly been found in the Company's talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, and (iii) the Company never adopted concentration methods that could detect the asbestos.

#### **July 2013 False and Misleading Statements**

99. During a July 16, 2013 conference call regarding the Company's 2Q13 results, the Company provided more assurance to investors that the Company paid careful attention to the safety of its products and that as part of a "quality initiative," the Company was identifying problems early and was correcting them:

[Sandy Peterson, Group Worldwide Chairman:] [O]ur quality effort is across the enterprise, across all of our businesses, our manufacturing sites as well as all of our R&D sites, because they are under the scope of *trying to ensure that we have the highest standard of quality for the safety and care of our patients and consumers*. So, when we launched the quality initiative a number of years ago, the focus really was on ensuring that we've got consistent quality standards. . . .

. . . And we have, obviously as we've gone through all of this work, *we have identified corrective actions, and we've immediately taken those corrective actions*.

. . . We're putting in place processes and systems so that *we have early warning systems in place to understand if we think there may be something going on with a product. So we identify it early and we go out and correct it.*

In addition to that, an important component of all of this is how we're managing our global supply chain. So, one of the very important changes that we have been making with our global supply chain *is ensuring that all of our external suppliers – so, our material suppliers* – are thoroughly reviewed, are thoroughly managed, and that they are living up to our quality standards. And in that process in the last three years we've actually consolidated our external manufacturing, our external material suppliers by about one-third. So we have one-third less than we had three years ago. That means that we have an ability to manage them much more effectively, and ensure that we are reviewing their quality of their products coming into our facilities. [Emphasis added].

100. Defendants' statements above that the Company was "trying to ensure . . . the highest standard of quality for . . . safety" identifying problems early and correcting them "immediately," and "ensuring that [its] . . . external suppliers [were] living up to [J&J's] quality standards" were false and misleading. In truth, Defendants were continuing the Company's campaign to conceal the dangers inherent in its talcum powders. Indeed, Peterson failed to disclose that (i) asbestos had repeatedly been found in the Company's talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, and (iv) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation.

#### **August to November 2013 False and Misleading Statements**

101. On August 1, 2013, Defendants caused the Company to file its 2Q13 Form 10-Q with the SEC. According to Defendants, the Company "remain[ed] committed" to "delivering high quality" and "improving existing products":

#### **Research and Development Expense**

Research and development activities represent a significant part of the Company's business. These expenditures relate to the processes of discovering, testing and developing new products, *improving existing products*, as well as ensuring product

efficacy and regulatory compliance prior to launch. *The Company remains committed to investing in research and development with the aim of delivering high quality and innovative products.* [Emphasis added].<sup>7</sup>

102. The Company's 2Q13 10-Q disclosed that some of the Company's subsidiaries were involved in product liability litigation, but also represented that the warnings and instructions accompanying their products were adequate:

Certain subsidiaries of Johnson & Johnson are involved in numerous product liability cases. The damages claimed are substantial, and while *these subsidiaries are confident of the adequacy of the warnings and instructions for use that accompany the products at issue*, it is not feasible to predict the ultimate outcome of litigation. The Company has established product liability accruals in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. Changes to the accruals may be required in the future as additional information becomes available. [Emphasis added].<sup>8</sup>

103. Defendants' statements above were false and misleading. While Defendants boasted of "improving existing products," being "committed to investing in research and development with the aim of delivering high quality. . . products," and having "adequate" warnings, they omitted that (i) asbestos had repeatedly been found in the Company's talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, and (iii) the Company never adopted concentration methods that could detect the asbestos.

#### **January 2014 False and Misleading Statements**

104. By January 7, 2014, the Company's "Our Safety & Care Commitment" website stated the following<sup>9</sup>:

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<sup>7</sup> These statements were also made in the Company's third quarter of 2013 ("3Q13") Form 10-Q, filed November 4, 2013.

<sup>8</sup> These statements were also made in the Company's 3Q13 Form 10-Q, filed November 4, 2013.

<sup>9</sup> Our Safety & Care Commitment, Johnson & Johnson Family of Consumer Companies, <http://www.safetyandcarecommitment.com:80/ingredientinfo/other/Talc>.



*Few ingredients have demonstrated the same performance, mildness and safety profile as cosmetic talc, which has been used for over 100 years by millions of people around the world.* Talcum powder is made from the mineral, talc. In a powder form, talc helps reduce friction, making it useful for keeping skin dry and helping to prevent rashes. Talc is a common natural ingredient found in cosmetic products such as baby powder and adult body and facial powders, and in a range of other consumer products such as toothpaste, chewing gum, and aspirin.

JOHNSON’S® Baby talc products are made using U.S. Pharmacopeial (USP) grade talc to *ensure it meets the highest-quality, purity and compliance standards. Our talc is carefully selected, processed and tested to ensure that [it] is asbestos free, as confirmed by regular testing conducted since the 1970s.*

\* \* \*

At the Johnson & Johnson Family of Consumer Companies, *our confidence in using talc is based on a long history of safe use and more than 30 years of research by independent researchers, scientific review boards and global regulatory authorities. Various agencies and governmental bodies have examined whether talc is a carcinogen, and none have concluded that it is. These include the U.S. Food and Drug Administration (FDA) and National Toxicology Program, part of the U.S. Department of Health and Human Services.*

\* \* \*

Many research papers and epidemiology studies have been published since the early 1990s studying talc and perineal use and *these studies have found talc to be safe. A detailed meta-analysis* done by Muscat in 2007, reviewed all available data and showed no cause and effect relationship between perineal use and ovarian cancer. [Emphasis added].<sup>10</sup>

105. Defendants’ statements above were false and misleading. Defendants knew that talc did not have “a long history of safe use” after being “used for over 100 years.” These statements, as well as the representations regarding talc’s “safety profile” and “purity,” the representation that “[o]ur talc is carefully selected, processed and tested to ensure that [it] is asbestos free,” and the representation that “regular testing conducted since the 1970s” confirmed that the Company’s talc

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<sup>10</sup> Citing Muscat, Perineal talc use and ovarian cancer risk: a case study of scientific standards in environmental epidemiology, Eur. J. of Cancer Prevention, Nov. 11, 2011, <http://www.ncbi.nlm.nih.gov/pubmed/21712717>.



was asbestos free, were false and misleading as they omitted that (i) asbestos had repeatedly been found in the Company's talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, and (iii) the Company never adopted concentration methods that could detect the asbestos.

106. Defendants' representations that "more than 30 years of research by independent researchers, scientific review boards and global regulatory authorities" supported the safety of talc, that studies "since the early 1990s . . . have found talc to be safe," and that "none" of the "[v]arious agencies and governmental bodies" have concluded that talc is a carcinogen, were false and misleading. Defendants acknowledged internally that other scientific sources not included on the website were actually "not as definitive or supportive and could be interpreted as suggesting a causal effect" and that "[e]ven some of the studies we cite send mixed messages." Defendants knew that one of the studies cited by the Company even admitted that "'perineal talc use may modestly increase the risk of invasive serous ovarian cancers.'" In addition, the statements omitted that (i) asbestos had repeatedly been found in the Company's talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, and (iv) the Company had purposely influenced and manipulated regulators and scientists, including the FDA and NTP, in order to protect the Company's flagship product and reputation.

107. On a January 21, 2014 conference call discussing the Company's 4Q13 and FY13 results, Defendant Gorsky told investors that the Company's Chief Medical and Chief Quality Officers were "setting new benchmarks for medical safety" and were ensuring the Company's products were safe:

***Our Chief Medical and Chief Quality Officers are setting new benchmarks for medical safety and implementing a more consistent global approach for monitoring***

*the use of our end market products that is very patient- and consumer-centric for ensuring that they are safe and performing* as expected and as intended. While we're pleased with the progress that we've made here, we're not yet satisfied and *we'll keep doing whatever it takes to ensure that we continue to earn the trust of consumers and patients around the world.* [Emphasis added].

108. Defendants' statements above that the Company had done and would continue to do "whatever it takes to ensure . . . the trust of consumers and patients," including "setting new benchmarks for medical safety" and "ensuring that the Company's products "are safe," were false and misleading. In truth, Defendants were continuing the longstanding campaign to conceal the dangers inherent in the Company's talcum powders. Indeed, Defendants failed to disclose that (i) asbestos had repeatedly been found in the Company's talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, and (iv) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation.

#### **February to October 2014 False and Misleading Statements**

109. On February 21, 2014, Defendants caused the Company to file its 2013 10-K with the SEC. The 2013 10-K again represented that the Company "remain[ed]" committed" to "delivering high quality" and "improving existing products":

##### ***Research and Development***

Research and Development activities represent a significant part of the Company's business. [Research and development] expenditures relate to the processes of discovering, testing and developing new products, *improving existing products*, as well as ensuring product efficacy and regulatory compliance prior to launch. *The Company remains committed to investing in research and development with the aim of delivering high quality* and innovative products. [Emphasis added].

110. Exhibit 13 to the 2013 10-K disclosed that some of its subsidiaries were involved in product liability litigation, but also represented that the subsidiaries had "substantial defenses":

Certain subsidiaries of Johnson & Johnson are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. While ***these subsidiaries believe they have substantial defenses***, it is not feasible to predict the ultimate outcome of litigation. The Company has established product liability accruals in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. Changes to the accruals may be required in the future as additional information becomes available. [Emphasis added].

111. On May 2, 2014, Defendants caused the Company to file its first quarter of 2014 (“1Q14”) Form 10-Q with the SEC. According to Defendants, the Company “remain[ed]” committed” to “delivering high quality” and “improving existing products”:

***Research and Development Expense***

Research and development activities represent a significant part of the Company’s business. These expenditures relate to the processes of discovering, testing and developing new products, ***improving existing products***, as well as ensuring product efficacy and regulatory compliance prior to launch. ***The Company remains committed to investing in research and development with the aim of delivering high quality and innovative products.*** [Emphasis added].

112. The Company’s 1Q14 10-Q disclosed that some of the Company’s subsidiaries were involved in product liability litigation, but also represented that the subsidiaries had “substantial defenses”:

Certain subsidiaries of Johnson & Johnson are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. While ***these subsidiaries believe they have substantial defenses***, it is not feasible to predict the ultimate outcome of litigation. The Company has established product liability accruals in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. Changes to the accruals may be required in the future as additional information becomes available. [Emphasis added].<sup>11</sup>

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<sup>11</sup> These statements were also made in the Company’s 2Q14 and third quarter of 2014 (“3Q14”) Form 10-Qs (filed August 1, 2014 and October 30, 2014, respectively).

113. On August 1, 2014, Defendants caused the Company to file its second quarter of 2014 (“2Q14”) Form 10-Q with the SEC. According to Defendants, the Company “remain[ed]” committed” to “delivering high quality”:

**Research and Development Expense**

*The Company remains committed to investing in research and development with the aim of delivering high quality and innovative products.* [Emphasis added].

114. Defendants’ statements above were false and misleading. While defendants boasted of “improving existing products,” being “committed to investing in research and development with the aim of delivering high quality . . . products,” and of the Company’s subsidiaries having “substantial defenses,” they omitted that (i) asbestos had repeatedly been found in the Company’s talc and powder, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, and (iv) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company’s flagship product and reputation.

**January to February 2015 False and Misleading Statements**

115. During a JPMorgan Healthcare Conference on January 12, 2015, Defendant Gorsky stated:

*Quality and safety, our number-one priority* in dealing with patients and consumers. We’ve made a number of changes over the last few years, frankly to *make sure that we addressed any of the outstanding issues that we were facing*, but also more importantly to set us up for a benchmark going forward. [Emphasis added].

116. On February 5, 2015, Defendant Glasgow created a page on the Company’s website entitled “Making Every Moment Matter.” She represented that the Company understood and cared about the needs of babies and that the Company “look[ed] at all the science” “that help our babies thrive and grow”:

As a mom, I understand the need for other moms and dads to treasure the precious moments throughout the day we get to spend with our children. From bath time to bedtime, all of these moments turn into our very own special rituals and serve as a way to bond and develop a relationship with our little ones. What may come as a surprise to some is how all of these everyday interactions serve as the perfect opportunity to stimulate your baby's senses, which we believe can have a positive impact on their development.

Working on JOHNSON'S®, I've had the chance to meet parents all over the world and look at the unique rituals and practices between them and their baby. What I found to be universal is the desire for families to raise happy, healthy babies.

*As the first baby care brand to commit to advancing the science of baby's skin, we feel, as scientists, an obligation to continue to take our research to the next level by looking at all the science – even beyond the science focused on cleansing – that help our babies thrive and grow.* It's why I am so excited about the new and existing research we are sharing that reveals the importance of multi-sensorial experiences that can lead to happy, healthy baby development.

By age three, 85% of a baby's brain is developed so it's no surprise that every experience leading up to this time helps to shape their brain. From the nighttime cuddles to the bath time bubble splashing sessions, all of these interactions are giving you *an opportunity to nurture your baby's ability to learn*, think, love and grow. And even more interesting is how the brain's processes for learning are enhanced when multiple senses are stimulated versus just using one. It's *why I spend a lot of time looking at how touch and smell work together so we can help families make the little moments – like bath time (and what I like to call a sensorial playground) – mean so much more.*

Looking into the future, JOHNSON'S® has earmarked millions of dollars over the next three years to advance new research and will continue to partner with leading experts in the space to uncover even more about the “science of the senses.” [Emphasis added].

117. Defendants' statements above that “[q]uality and safety [were J&J's] number-one priority” and that the Company had “addressed any of the outstanding issues that [it was] facing,” were false and misleading. In truth, the Company continued its longstanding fraudulent scheme to protect the image of Baby Powder's safety and the Company's reputation, concealing that (i) asbestos had repeatedly been found in the Company's talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted

concentration methods that could detect the asbestos, and (iv) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation.

118. Defendants' statements that the Company "continue[d] to take [its] research to the next level by looking at all the science . . . that help our babies thrive and grow" and that the Company "help[ed] families make the little moments – like bath time" serve as "an opportunity to nurture your baby's ability to learn," were similarly false and misleading. Instead of "looking at all the science" or helping families nurture their babies, the Company had provided parents with the opportunity to unwittingly expose their children to asbestos, while the Company continued to reject appropriate testing methods and ignored the multiple findings of asbestos in its talc powders. Defendants concealed that (i) asbestos had repeatedly been found in the Company's talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, and (iv) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation.

119. On February 24, 2015, Defendants caused the Company to file its 2014 10-K with the SEC ("2014 10-K"). The 2014 10-K again represented that the Company "remain[ed]" committed" to "delivering high quality" and "improving existing products":

#### **Research and Development**

Research activities represent a significant part of the Company's businesses. Research and development expenditures relate to the processes of discovering, testing and developing new products, *improving existing products*, as well as demonstrating product efficacy and regulatory compliance prior to launch. *The Company remains committed to investing in research and development with the aim of delivering high quality and innovative products.* [Emphasis added].

120. Exhibit 13 to the 2014 10-K disclosed that some of its subsidiaries were involved in product liability litigation, but also represented that the subsidiaries “have substantial defenses”:

Certain subsidiaries of Johnson & Johnson are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. While *these subsidiaries believe they have substantial defenses*, it is not feasible to predict the ultimate outcome of litigation. The Company has established product liability accruals in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. In addition, product liability accruals can represent projected product liability for thousands of claims around the world, each in different litigation environments and with different fact patterns. Changes to the accruals may be required in the future as additional information becomes available. [Emphasis added].

121. Defendants’ statements above were false and misleading. While Defendants boasted of “improving existing products,” being “committed to investing in research and development with the aim of delivering high quality . . . products,” and of the Company’s subsidiaries having “substantial defenses,” they omitted that (i) asbestos had repeatedly been found in the Company’s talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, and (iv) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company’s flagship product and reputation.

#### **April 2015 False and Misleading Statements**

122. At an April 23, 2015 Shareholders Meeting, Defendant Gorsky assured investors that the Company was taking care of mothers and babies:

Johnson & Johnson is committed to helping mothers and babies, we never want to forget the needs of the world’s smallest patients.

\* \* \*

Caring inspires us day in and day out as we strive to make a difference for people who count on us the most. And as the world’s largest and best healthcare company in



the world, we're committed to reaching more people in more places in more ways. We're helping people ultimately live longer, healthier, and happier lives.

123. Defendants' statements above were false and misleading. Instead of being committed to mothers and babies, helping people live longer and happier lives, or "striv[ing] to make a difference for people," Defendants were continuing the Company's longstanding fraudulent scheme to protect the image of Baby Powder's and the Company's reputation, concealing that (i) asbestos had repeatedly been found in the Company's talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, and (iv) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation. Despite the numerous red flags raised internally at the Company, the Company continued to sell its talcum powders and failed to use proper methods for testing its talc.

#### **May to October 2015 False and Misleading Statements**

124. On May 1, 2015, Defendants caused the Company to file its first quarter of 2015 ("1Q15") Form 10-Q with the SEC. Defendants disclosed that some of the Company's subsidiaries were involved in product liability litigation, but also represented that the subsidiaries had "substantial defenses":

Certain subsidiaries of Johnson & Johnson are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. While *these subsidiaries believe they have substantial defenses*, it is not feasible to predict the ultimate outcome of litigation. The Company has established product liability accruals in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. In addition, product liability accruals can represent projected product liability for thousands of claims around the world, each in different litigation environments and with different fact patterns. Changes to the



accruals may be required in the future as additional information becomes available.  
[Emphasis added].<sup>12</sup>

125. Defendants' statements above were false and misleading. While Defendants boasted of the Company's subsidiaries having "substantial defenses," they omitted that (i) asbestos had repeatedly been found in the Company's talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, and (iv) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation.

#### **December 2015 False and Misleading Statements**

126. As of December 25, 2015, the Company had updated its website entitled "Our Safety & Care Commitment," stating the following:

***Any amount of talc used in a consumer product is required to be asbestos-free and has been since the 1970s – though misperceptions still exist that talc products contain asbestos, a substance with links to cancer. JOHNSON'S® Baby Powder products contain only U.S. Pharmacopeial (USP) grade talc which meets the highest quality, purity and compliance standards. The talc used in all our global products is carefully selected and processed to be asbestos-free, and we confirm this with regular testing. The U.S. Food and Drug Administration (FDA) has also tested and confirmed the purity of our talc.***

Another misperception is that talc in baby powder can be easily inhaled or absorbed into the body. We always recommend not using talc around a baby's face or mouth, and to further protect your baby, ***we precisely mill our JOHNSON'S talc products to a relatively large size to decrease the potential to be inhaled or absorbed into the body.***

#### **Decades of Safety**

Our confidence in using talc reflects ***more than 30 years of research by independent scientists, review boards and global authorities, which have concluded that talc can be used safely in personal care products. Various government agencies and other***

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<sup>12</sup> These statements were also made in the Company's second quarter of 2015 ("2Q15") and third quarter of 2015 ("3Q15") Form 10-Qs (filed July 31, 2015 and October 30, 2015, respectively).

***bodies also have examined talc to determine the potential for any safety risks, and none have concluded that there are safety risks.*** In fact, no regulatory agency has ever required a change in labeling to reflect any safety risk from talc powder products.

\* \* \*

Among the agencies that have examined talc are the U.S. Department of Health and Human Services and the U.S. FDA. As recently as 2014, the FDA again reviewed the safety data on talc and did not find “any new compelling literature data or new scientific evidence.”

***Cosmetic talc is not included in the most recent Report on Carcinogens, which is published by the U.S. National Toxicology Program (NTP).*** NTP is a globally recognized program and is formed from parts of several different government agencies, including the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA).

In addition to government health authorities, our own toxicology teams are also responsible for evaluating any new research published on talc, and ***at times we may ask outside experts for an independent perspective on new or existing studies. We have carefully assessed all available data on talc and consumers can feel confident that the overwhelming body of research and clinical evidence continues to support the safety of cosmetic talc.***

\* \* \*

### **Our Position on Talc**

At Johnson & Johnson Consumer Inc., our confidence in using talc is based on a ***long history of safe use and more than 30 years of research by independent researchers, scientific review boards and global regulatory authorities. Various agencies and governmental bodies have examined whether talc is a carcinogen, and none have concluded that it is. With over 100 years of use, few ingredients have the same demonstrated performance, mildness and safety profile as cosmetic talc.*** [Emphasis added].

127. Defendants’ statements above were false and misleading. Defendants knew that talc did not have “a long history of safe use” after “over 100 years of use.” In addition, the representations regarding talc’s “safety profile,” “purity,” and asbestos-free nature, the representation that the Company’s talc is “precisely milled” and “carefully selected and processed to be asbestos-free, [confirmed] with regular testing,” and the representation that “[a]ny amount of talc

used in a consumer product is required to be asbestos-free and has been since the 1970s” were false and misleading as they omitted that: (i) asbestos had repeatedly been found in the Company’s talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, and (iii) the Company never adopted concentration methods that could detect the asbestos.

128. Defendants’ representations that: (i) “more than 30 years of research by independent scientists, review boards and global authorities” supported the safety of talc, (ii) “the overwhelming body of research and clinical evidence” supports cosmetic talc’s safety, (iii) “consumers can feel confident” about the safety of talc based on the Company’s “careful[] assess[ment] [of] all available data,” and (iv) “none” of the “[v]arious government agencies and other bodies” have concluded there are any safety risks with talc usage, were false and misleading when made. Defendants acknowledged internally that scientific sources not included on the website were actually “not as definitive or supportive and could be interpreted as suggesting a causal effect” and that “[e]ven some of the studies we cite send mixed messages.” And, Defendants acknowledged internally that even one of the studies cited by the Company admitted that ““perineal talc use may modestly increase the risk of invasive serous ovarian cancers.”” In addition, these statements, as well the statement regarding “outside experts [with] independent perspective[s],” omitted that (i) asbestos had repeatedly been found in the Company’s talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, and (iv) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company’s flagship product and reputation.

129. Similarly, Defendants’ statement regarding the FDA was materially misleading, as the website failed to disclose that the Company had falsely assured the FDA that its talc and powders were free of asbestos. And, Defendants’ statement regarding the absence of talc in the RoC omitted

the Company's own internal recognition that this was a "direct result" of the Company's efforts at influencing regulators.

130. The "Our Safety and Care Commitment" website also contained the following statement from Defendant Casalvieri, Director of Toxicology and Skincare, JJCI:

As a toxicologist in our Consumer business, my job is to make certain a product is safe by assessing whether any ingredient in that product poses a risk. ***We want to assure women and caregivers who use our talc products that numerous studies support its safety, and these include assessments by external experts in addition to our company testing. Many research papers and epidemiology studies have specifically evaluated talc and perineal use and these studies have found talc to be safe.*** [Emphasis added].

131. The statements by Defendant Casalvieri above were false and misleading. While Casalvieri represented that "company testing," "numerous studies" and "assessments by external experts" support[ed] [talc's] safety," and that "[m]any research papers and epidemiology studies . . . have found talc to be safe," she omitted that (i) asbestos had repeatedly been found in the Company's talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, and (iv) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation.

#### **February 2016 False and Misleading Statements**

132. In a February 23, 2016 *Reuters* article, Company spokeswoman Goodrich was quoted:

We have no higher responsibility than the health and safety of consumers, and we are disappointed with the outcome of the trial. We sympathize with the plaintiff's family but ***firmly believe the safety of cosmetic talc is supported by decades of scientific evidence.*** [Emphasis added].

133. But the statement by Goodrich above was false and misleading. Defendants acknowledged internally that some of the scientific sources were actually "not as definitive or

supportive and could be interpreted as suggesting a causal effect” between ovarian cancer and talc and that “[e]ven some of the studies we cite send mixed messages.” Defendants acknowledged internally that even one of the studies cited by the Company admitted that ““perineal talc use may modestly increase the risk of invasive serous ovarian cancers.”” In addition, the statement was false and misleading in that it failed to disclose that (i) asbestos had repeatedly been found in the Company’s talc and powder, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, and (iv) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company’s flagship product and reputation.

134. On February 24, 2016, Defendants caused the Company to file its 2015 10-K with the SEC (“2015 10-K”). The 2015 10-K again represented that the Company “remain[ed]” committed” to “delivering high quality” and “improving existing products”:

Research activities represent a significant part of the Company’s businesses. Research and development expenditures relate to the processes of discovering, testing and developing new products, *improving existing products*, as well as demonstrating product efficacy and regulatory compliance prior to launch. *The Company remains committed to investing in research and development with the aim of delivering high quality and innovative products.* [Emphasis added].

135. In its 2015 10-K, Defendants disclosed that some of the Company’s subsidiaries were involved in product liability litigation, but also represented that they had “substantial defenses”:

Certain subsidiaries of Johnson & Johnson are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. *While these subsidiaries believe they have substantial defenses*, it is not feasible to predict the ultimate outcome of litigation. The Company has established accruals for product liability claims and lawsuits in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. The Company accrues an estimate of the legal defense costs needed to defend each matter. For certain of these matters, the Company has accrued additional amounts such as estimated costs associated with settlements, damage and other losses. Product liability accruals can represent projected product liability for thousands of claims around the world, each

in different litigation environments and with different fact patterns. Changes to the accruals may be required in the future as additional information becomes available. [Emphasis added].

136. Defendants’ statements above were false and misleading. While Defendants boasted of “improving existing products,” being “committed to investing in research and development with the aim of delivering high quality . . . products,” and of the Company’s subsidiaries having “substantial defenses,” they omitted that: (i) asbestos had repeatedly been found in the Company’s talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, and (iv) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company’s flagship product and reputation.

137. On February 24, 2016, the Company created a page on its website entitled “The Facts About Talc Safety.” The Company stated:

Baby Powder made from cosmetic talc is one of JOHNSON’s oldest products and a longtime part of baby care rituals. JOHNSON’s Baby Powder continues to be popular with adults as well, and in many parts of the world, it remains an essential part of the makeup and skin care routines. ***With over 100 years of use, few ingredients have the same demonstrated performance, mildness and safety profile as cosmetic talc.***

We wanted to take this opportunity to share the facts about talc, ***so you’re well-informed.***

- ***JOHNSON’s talc products do not contain asbestos.*** A frequent misperception is that JOHNSON’s Baby Powder contains talc made with asbestos, a substance classified as cancer-causing. ***Since the 1970s, talc used in consumer products has been required to be asbestos-free.*** JOHNSON’S® Baby Powder products contain only U.S. Pharmacopeia (USP) grade talc, which meets the highest quality, purity and compliance standards.
- ***The safety of talc is based on a long history of safe use and decades of research by independent researchers and scientific review boards.*** Talc is accepted as safe for use in cosmetic and personal care products by the European Union, Canada and many other countries around the world, among them Argentina, Brazil, China, India, Israel, South Africa, Turkey and

Indonesia. The U.S. Center for Disease Control (CDC), which identifies potential risk factors for many diseases, has not identified talc as a risk factor for ovarian cancer.

- The Nurses' Health Study (2010) and the Women's Health Initiative Observational Cohort (2014), the only two large-scale prospective studies looking at talc and ovarian cancer, found no causal relationship between talc and ovarian cancer.

\* \* \*

*The grade of talc used in cosmetics is of high purity, comparable to that used for pharmaceutical applications, and is free from asbestos and asbestiform fibers. Cosmetic grade talc is only mined from select deposits from certified locations, and milled to relatively large, non-respirable particles size.*

\* \* \*

*Our sources for talc undergo comprehensive qualification. The incoming talc is routinely evaluated using a sophisticated battery of tests designed to ensure quality, safety, and compliance with all global standards.* [Emphasis added].

138. Defendants' statements above were false and misleading and were not written and communicated to keep investors "well-informed." While Defendants' claimed that cosmetic talc had "over 100 years of use," the Company's own internal document acknowledges that "I don't think we can link cosmetic talc to 100 years of use." This statement was false and misleading for other reasons, as were the representations (i) regarding talc's "long history of safe use," "safety profile," and "high purity," (ii) that cosmetic talc "is free from asbestos and asbestiform fibers," "only mined from select deposits from certified locations," and "milled to relatively large, non-respirable particles size," (iii) that talc used in consumer products "has been required to be asbestos-free" "[s]ince the 1970s," (iv) that the Company's "sources for talc undergo comprehensive qualification" and that "incoming talc is routinely evaluated using a sophisticated battery of tests designed to ensure . . . safety," (v) the Company's "talc products do not contain asbestos," and (vi) that it is a "misperception . . . that JOHNSON'S Baby Powder contains talc made with asbestos." These



statements concealed that (i) asbestos had repeatedly been found in the Company's talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, and (iv) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation. In addition, Defendants' statements created the impression that the Company's talc has always been asbestos-free but knew internally that "we cannot say 'always.'"

139. Defendants' representation that "decades of research by independent researchers and scientific review boards" supported "[t]he safety of talc," was also false and misleading, as Defendants omitted that the Company acknowledged internally that some of the scientific sources were actually "not as definitive or supportive and could be interpreted as suggesting a causal effect" between ovarian cancer and talc and that "[e]ven some of the studies we cite send mixed messages." The Company internally acknowledged that one of the studies cited by the Company admitted that "perineal talc use may modestly increase the risk of invasive serous ovarian cancers." In addition, the statement about "decades of research" was false and misleading because it failed to disclose that (i) asbestos had repeatedly been found in the Company's talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, and (iv) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation.

#### **May 2016 False and Misleading Statements**

140. On May 2, 2016, Defendants caused the Company to make the following representations in a press release posted on the Company's website:

Unfortunately, *the jury's decision goes against 30 years of studies by medical experts around the world that continue to support the safety of cosmetic talc.* We



understand that women and families affected by ovarian cancer are searching for answers, and we deeply sympathize with all who have been affected by this devastating disease with no known cause. ***Johnson & Johnson has always taken questions about the safety of our products extremely seriously. Multiple scientific and regulatory reviews have determined that talc is safe for use in cosmetic products and the labeling on Johnson's Baby Powder is appropriate. For over 100 years, Johnson & Johnson has provided consumers with a safe choice for cosmetic powder products and we will continue to work hard to exceed consumer expectations and evolving product preferences.*** [Emphasis added].

141. On May 2, 2016, the Company published “A Message About Talc” on its website. In the release, the Company again promised that its talc products were safe – omitting any mention of asbestos – and assured that the Company “did the things you expect from a company you trust”:

***30 years of studies by medical experts around the world, science, research and clinical evidence continues to support the safety of cosmetic talc. We first offered JOHNSON'S® Baby Powder as a product choice more than 100 years ago because we were confident in the safety of talc.*** And today, we continue to manufacture and sell JOHNSON'S® Baby Powder with talc because we remain completely confident in its safety. We remain committed to safety and innovation and will continue to work hard to exceed consumer expectations and evolving product preferences. This commitment to innovation led to the introduction of JOHNSON'S® Baby Powder made with cornstarch as an additional option for consumers nearly forty years ago.

Everyone at Johnson & Johnson sympathizes deeply with the women and families who have been affected by ovarian cancer, a devastating disease with no known cause. We know the women and families affected are searching for answers and want to understand the science.

### **Safety**

***When concerns about an association between talc and ovarian cancer were first raised in the early 1980s, Johnson and Johnson took them very seriously and did the things you expect from a company you trust including:***

- ***Testing to ensure*** that the talc in JOHNSON'S® Baby Powder meets the highest Quality standards (US Pharmacopeia)
- ***Engaging with the FDA***, regulatory agencies, and governments around the world
- ***Monitoring studies and all available information*** examining the safety of talc

- ***Talking with independent consultants*** from outside our company about their point of view on the safety of talc.

***After 30 years of studies by medical experts around the world, science, research and clinical evidence continues to support the safety of cosmetic talc.*** Two widely-accepted, very large studies which followed women over a period of time – the Nurses’ Health Study by the Harvard School of Public Health published in 2009 and the Women’s Health Initiative Observational Cohort by the U.S. National Institutes of Health published in 2014 – found no association between talc and ovarian cancer. We also know that some epidemiology studies have reported an association between talc and ovarian cancer. However, ***various governmental and non-governmental agencies as well as other expert panels have reviewed and analyzed all available data, and none have concluded that talc can cause cancer.***

Concerns about the possible association between cosmetic talc with ovarian cancer increased after recent jury verdicts in the United States. It is natural for trial verdicts to raise questions about the product involved, and it’s also important to distinguish jury verdicts – in the United States – from regulatory rulings or rigorous scientific findings. ***Johnson & Johnson has always taken questions about the safety of our products extremely seriously,*** especially concerns about products like JOHNSON’S® Baby Powder that families have trusted for generations. We continue to believe in the safety of JOHNSON’S® Baby Powder containing talc and we trust our consumers to make their own decisions – which are why we want to provide the scientific support for the safety of talc. Our goal is always to meet our consumer’s needs and we are fortunate to have had this opportunity for more than 130 years. [Emphasis added].

142. Defendants’ statements above that “Johnson & Johnson has provided consumers with a safe choice for cosmetic powder products” “[f]or over 100 years,” and that the Company first sold Baby Powder “more than 100 years ago because we were confident in the safety of talc” and “we remain completely confident in its safety,” were false and misleading. In truth, the Company acknowledged internally that its talcum powders had not been “safe” for over 100 years, and indeed, the Company could not even “link cosmetic talc to 100 years of use.” The statements also created the impression that the Company’s talc has historically been safe, when in fact the Company knew that when it came to asbestos in the Company’s talcum powders, it could not say it was ““always”” asbestos-free. These statements were false and misleading because they omitted that: (i) asbestos had repeatedly been found in the Company’s talc and powders, (ii) the Company had attempted to

find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, and (iv) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation.

143. Defendants' statements above that (i) "30 years of studies by medical experts around the world" "science, research and clinical evidence" "support the safety of cosmetic talc," (ii) "[m]ultiple scientific and regulatory reviews have determined that talc is safe . . . and the labeling on Johnson's Baby Powder is appropriate," and (iii) out of "various governmental and non-governmental agencies" and "expert panels," "none have concluded that talc can cause cancer" even after they "reviewed and analyzed all available data," were false and misleading. Defendants knew that some scientific sources "could be interpreted as suggesting a causal effect" and that "[e]ven some of the studies [it] cite[d] send mixed messages." Further, Defendants knew that research it cited had actually determined that "'perineal talc use may modestly increase the risk of invasive serous ovarian cancers.'" These statements were also false and misleading because they omitted that: (i) asbestos had repeatedly been found in the Company's talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, (iv) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation, and (v) the Company had misled the FDA less than two months prior.

144. Defendants' representations that (i) "Johnson & Johnson has always taken questions about the safety of [Johnson's Baby Powder] extremely seriously," (ii) the Company "remain[ed] committed to safety," and (iii) the Company took "concerns about an association between talc and ovarian cancer" "very seriously and did the things you expect from a company you trust," including testing, engaging with the FDA and other regulators, monitoring "all available information," and

“[t]alking with independent consultants,” were also false and misleading. These statements omitted that: (i) asbestos had repeatedly been found in the Company’s talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, (iv) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company’s flagship product and reputation, and (v) the Company had misled the FDA less than two months prior.

145. On May 10, 2016, Defendants caused the Company to file its 1Q16 Form 10-Q with the SEC. Defendants disclosed that some of the Company’s subsidiaries were involved in product liability litigation but also represented that the subsidiaries had “substantial defenses”:

Certain subsidiaries of Johnson & Johnson are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. ***While these subsidiaries believe they have substantial defenses***, it is not feasible to predict the ultimate outcome of litigation. The Company has established accruals for product liability claims and lawsuits in compliance with ASC 450-20 based on currently available information, which in some cases may be limited.

The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated. For certain of these matters, the Company has accrued additional amounts such as estimated costs associated with settlements, damages and other losses. Product liability accruals can represent projected product liability for thousands of claims around the world, each in different litigation environments and with different fact patterns. Changes to the accruals may be required in the future as additional information becomes available.

\* \* \*

Claims for personal injury have been made against Johnson & Johnson Consumer Inc. and Johnson & Johnson arising out of the use of JOHNSON’S® Baby Powder. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Lawsuits have been primarily filed in state courts in Missouri and New Jersey. The Company has established an accrual for defense costs in connection with product liability litigation associated with JOHNSON’S® Baby Powder. Changes to this accrual may be required in the future as additional information becomes available. [Emphasis added].

146. Defendants' statements above were false and misleading. While Defendants boasted of the Company's subsidiaries having "substantial defenses" and disclosed the existence of talc-related litigation, they omitted that: (i) asbestos had repeatedly been found in the Company's talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, and (iv) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation.

147. On May 18, 2016, Ghaim, the Chief Technology Officer of J&J Consumer, made further assurances during the *Consumer and Medical Devices Business Review*:

I'm going to start by saying there's a general assumption that people have natural is safe and most of the data we have actually that's not true. So there is a balance in terms of what products, what type of safety do we need to continue to build.

And all of our products, especially when we start with Baby, the number of safety studies that we tend to do before we even put it in any of our product is a starting point. But we also understand that the natural trend continues to be a big opportunity.

So we're working to that in terms of not just picking naturals but make sure that there is a benefit to it, make sure that it's safe, make sure that we can source it the right way because that's one of the biggest challenges. You can get natural ingredients but you can't guarantee that one lot to the next is actually consistently safe.

So for us I think we can see the trend. But at the same time ***we're being very careful in terms of what raw materials we select***, what type of safety studies that are needed. Because more than anything else safety is the number one area that we need to continue to focus. [Emphasis added].

148. Defendants' representation that "we're being very careful in terms of what raw materials we select, what type of safety studies that are needed," was false and misleading. This statement concealed that: (i) asbestos had repeatedly been found in the Company's talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, and (iii) the Company never adopted concentration methods that could detect the asbestos.

### **June 2016 False and Misleading Statements**

149. On June 19, 2016, Defendant Glasgow, VP of R&D at JJCI, stated the following in an editorial in the Houston Chronical:

At Johnson & Johnson Consumer Inc., *we are guided by the medical facts and science when it comes to our products. Cosmetic talc is safe, and 30 years of scientific studies and regulatory reviews have shown this to be true.*

This counters the claims of so-called experts, paid to testify on behalf of plaintiffs, who say decisions by juries should trump the overwhelming scientific data.

We first offered Johnson's Baby Powder as a product choice more than 100 years ago. Today, we continue to manufacture and sell Johnson's Baby Powder with talc because *the science supports its safety.*

Ovarian cancer is a devastating disease, and we recognize that women and families affected by this disease are searching for answers and want to understand the science. When concerns about an association between talc use and ovarian cancer were raised, *we started doing the things you expect from a company you trust, including testing to ensure the talc in our products meets the highest quality standards, meeting with regulators and governments around the world, looking closely at the studies and available information, and talking with independent consultants.*

*The facts are clear. The studies, science, research and clinical evidence have continued to support the safety of cosmetic talc.* Most recently, two widely-accepted, very large studies which followed women over a long period of time – the Nurses' Health Study by the Harvard School of Public Health published in 2009 and the Women's Health Initiative Observational Cohort by the U.S. National Institutes of Health published in 2014 – found no association between talc use for feminine hygiene and ovarian cancer.

There have been some studies that reported an association between talc and ovarian cancer.

In my job as a scientist, terms and words matter when it comes to studies, and an "association" does not mean something causes a specific result. Additionally, *many in the scientific community have concluded that the data from those studies are inconclusive because of how the studies were conducted. Various governmental and non-governmental agencies, such as the U.S. Food and Drug Administration (FDA) and National Cancer Institute, as well as other expert panels have reviewed and analyzed the available data and concluded that there is insufficient evidence linking talc use to ovarian cancer.*

Johnson's Baby Powder products contain only U.S. Pharmacopeia grade talc to ensure *it meets the highest quality, purity and compliance standards. We also carefully select and process the talc used in all our global production to be asbestos-free, and have confirmed this with regular testing since the 1970s.* The U.S. FDA has also independently tested and confirmed the purity of the talc used in our cosmetic products.

We trust our consumers to make their own decisions, which is why we will continue to provide consumers with the facts. As a scientist, and most importantly, as a parent, I can tell you *the science is clear cosmetic talc is, and has been, safe for use and that is the most important guiding principle for every product Johnson & Johnson Consumer Inc. offers to consumers and patients.* [Emphasis added].

150. Defendants' representations that: (i) "[c]osmetic talc is safe," (ii) Johnson's Baby Powder's talc meets "the highest" purity standard, and (iii) the Company "carefully select[s] and process[es] the talc used in all [its] global production to be asbestos-free, and have confirmed this with regular testing since the 1970s," were false and misleading. These statements concealed that: (i) asbestos had repeatedly been found in the Company's talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, and (iii) the Company never adopted concentration methods that could detect the asbestos.

151. Defendants' representations that the Company did "the things you expect from a company you trust" "[w]hen concerns about an association between talc use and ovarian cancer were raised," including testing, meeting with regulators, looking at "available information," and talking with "independent consultants," (ii) the Company's Consumer Division is "guided by the medical facts and science," and (iii) safety "is the most important guiding principle for every product Johnson & Johnson Consumer Inc. offers to consumers and patients," were false and misleading. These statements concealed that: (i) asbestos had repeatedly been found in the Company's talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, and (iv) the Company



had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation.

152. Defendants' representations that: (i) "30 years of scientific studies and regulatory reviews" have shown that "[c]osmetic talc is safe," (ii) "the science supports [Johnson's Baby Powder's] safety," (iii) "[t]he facts are clear" that "[t]he studies, science, research and clinical evidence have continued to support the safety of cosmetic talc," (iv) "the science is clear – cosmetic talc is, and has been, safe for use," and (v) "[v]arious governmental and non-governmental agencies [including the FDA], as well as other expert panels, have reviewed and analyzed the available data and concluded that there is insufficient evidence linking talc use to ovarian cancer," were false and misleading. Defendants knew that some scientific sources were actually "not as definitive or supportive and could be interpreted as suggesting a causal effect" between ovarian cancer and talc and that "[e]ven some of the studies we cite send mixed messages." Defendants acknowledged internally that even one of the studies it cited had determined that "perineal talc use may modestly increase the risk of invasive serous ovarian cancers." In addition, the statements failed to disclose that: (i) asbestos had repeatedly been found in the Company's talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, (iv) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation, and (v) the Company had misled the FDA less than three months prior.

#### **August to November 2016 False and Misleading Statements**

153. On August 4, 2016, Defendants caused the Company to file its second quarter of 2016 ("2Q16") Form 10-Q with the SEC. Defendants disclosed that the Company and some of the



Company's subsidiaries were involved in product liability litigation, but also represented that the Company had "substantial defenses":

Johnson & Johnson and certain of its subsidiaries are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. While *the Company believes it has substantial defenses*, it is not feasible to predict the ultimate outcome of litigation. The Company has established accruals for product liability claims and lawsuits in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated. For certain of these matters, the Company has accrued additional amounts such as estimated costs associated with settlements, damages and other losses. Product liability accruals can represent projected product liability for thousands of claims around the world, each in different litigation environments and with different fact patterns. Changes to the accruals may be required in the future as additional information becomes available.

Claims for personal injury have been made against Johnson & Johnson Consumer Inc. and Johnson & Johnson arising out of the use of JOHNSON'S® Baby Powder. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Lawsuits have been primarily filed in state courts in Missouri and New Jersey. The Company has established an accrual for defense costs in connection with product liability litigation associated with JOHNSON'S® Baby Powder. Changes to this accrual may be required in the future as additional information becomes available. [Emphasis added].

154. On November 4, 2016, Defendants caused the Company to file its third quarter of 2016 ("3Q16") Form 10-Q with the SEC. Defendants again disclosed that the Company and some of the Company's subsidiaries were involved in product liability litigation, but also represented that the Company had "substantial defenses":

Johnson & Johnson and certain of its subsidiaries are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. While *the Company believes it has substantial defenses*, it is not feasible to predict the ultimate outcome of litigation. The Company has established accruals for product liability claims and lawsuits in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated. For certain of these matters, the Company has

accrued additional amounts such as estimated costs associated with settlements, damages and other losses. Product liability accruals can represent projected product liability for thousands of claims around the world, each in different litigation environments and with different fact patterns. Changes to the accruals may be required in the future as additional information becomes available.

\* \* \*

Claims for personal injury have been made against Johnson & Johnson Consumer Inc. and Johnson & Johnson arising out of the use of JOHNSON'S® Baby Powder. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Lawsuits have been primarily filed in state courts in Missouri, New Jersey and California. In addition, a federal multi-district litigation proceeding has been created for this litigation in the District Court of New Jersey. The Company has established an accrual for defense costs in connection with product liability litigation associated with JOHNSON'S® Baby Powder. Changes to this accrual may be required in the future as additional information becomes available. [Emphasis added].

155. Defendants' statements above were false and misleading. While Defendants boasted of having "substantial defenses" and disclosed the existence of talc-related litigation, they omitted that: (i) asbestos had repeatedly been found in the Company's talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, (iv) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation.

#### **December 2016 False and Misleading Statements**

156. On December 30, 2016, the Company touted the safety and effectiveness of talc in its products on its website<sup>13</sup> stating in pertinent part:

#### **In our products**

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<sup>13</sup> See <https://www.safetyandcarecommitment.com/Ingredients/Talc>.

We continue to use talc in our products because *decades of science have reaffirmed its safety*. Because of its safety and effectiveness, we confidently include pharmaceutical grade talc in our products. Your trust in our products and your confidence using them every day is a huge responsibility – that’s why *we only use ingredients in our products deemed safe by the latest science*.

*Science, research, clinical evidence and 30 years of studies by medical experts around the world continue to support the safety of cosmetic talc*. Health authorities in the U.S. and around the world have reviewed the data. Talc is accepted for . . . use in countries around the world, including the United States, European Union, Canada, Argentina, Brazil, China, India, Israel, South Africa, Turkey, and Indonesia.

When you read a new study or expert opinion, it’s easy to be swayed one way or another. *We take any questions about our product’s safety seriously* and as a result have dug deep into the evidence and science on talc. [Emphasis added].

157. Defendants’ statement above that the Company “take[s] any questions about [its] product’s safety seriously,” was false and misleading, as it concealed that: (i) asbestos had repeatedly been found in the Company’s talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, (iv) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company’s flagship product and reputation, and (v) the Company had misled the FDA in 2016.

158. Defendants’ assurances above that “decades of science have reaffirmed [the] safety” of “talc in [J&J’s] products,” “[s]cience, research, clinical evidence and 30 years of studies by medical experts around the world continue to support the safety of cosmetic talc,” and the Company “only use[s] ingredients in [its] products deemed safe by the latest science,” were false and misleading. Defendants knew that some scientific sources were actually “not as definitive or supportive and could be interpreted as suggesting a causal effect” between ovarian cancer and talc and that “[e]ven some of the studies we cite send mixed messages.” Defendants also knew that one of the studies it cited had determined that “perineal talc use may modestly increase the risk of invasive serous ovarian

cancers.’” In addition, the statements failed to disclose that: (i) asbestos had repeatedly been found in the Company’s talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, and (iv) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company’s flagship product and reputation.

### **January 2017 False and Misleading Statements**

159. On January 24, 2017, the Company’s website entitled “The facts on talcum powder safety” contained a statement by Glasgow, the VP of R&D at J&J’s consumer division. There, Glasgow omitted that the Company had received numerous reports of asbestos in its products:

When it comes to the safety of the products we make, we’re just like you . . .

We want all the information we can get. We seek out the guidance of experts and we monitor the latest science to see if it impacts any of our products. We also listen to the people who use our products so we can take their experiences into account. ***Safety is a priority for all of our consumer products because they go into your home and into ours. Safety is a value we all share.***

With all the types of information we use to make products, ***there is no information more important than our research on scientific data and safety.*** We go beyond the findings of a single study because we must ensure we’ve assembled ***all of the available data*** from multiple scientific areas to reach conclusions based on evidence. One opinion or study can’t outweigh ***decades of conclusive, scientific, evidence-based findings.*** As a scientist and, equally important, as a parent myself, ***I can tell you the science is clear: Cosmetic talc is, and has been, safe for use in consumer products.***

We are all mothers, fathers, and consumers ourselves; we understand and take seriously our responsibility to give you the information you need to make your own decisions. We created this site to help you find the facts about talc more easily. You’ll learn where talc comes from, how it is used in everyday products, and why ***it is safe to use as part of your personal care routine.*** We first offered JOHNSON’S® Baby Powder as a product choice more than 100 years ago. Today, our consumer division continues to manufacture and sell JOHNSON’S® Baby Powders with ingredients like talc and cornstarch. We choose to include these ingredients not simply because we’ve used them for decades. ***We include them because decades of scientific work support their safety.*** We hope that by reviewing this collection of facts about talc, you’ll feel as confident in its safety and efficacy as we do. [Emphasis added].

160. Defendants’ statements above that the Company made safety a priority and that “there is no information more important than . . . research on scientific data and safety,” were false and misleading. In truth, Defendants had and were continuing to conceal the dangers inherent in the Company’s talcum powders. Indeed, defendants failed to disclose that: (i) asbestos had repeatedly been found in the Company’s talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, (iv) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company’s flagship product and reputation, and (v) the Company had misled the FDA in 2016.

161. Defendants’ statements above that: (i) “all of the available data” and “decades of conclusive, scientific, evidence-based findings” supported the safety of cosmetic talc, (ii) “the science is clear: Cosmetic talc is, and has been, safe for use in consumer products,” (iii) talc “is safe to use as part of your personal care routine,” and (iv) “decades of scientific work” “support[s] [talc’s] safety,” were false and misleading. The Company acknowledged internally that some scientific sources were actually “not as definitive or supportive and could be interpreted as suggesting a causal effect” between ovarian cancer and talc and that “[e]ven some of the studies we cite send mixed messages.” Defendants knew that one of the studies it cited had determined that ““perineal talc use may modestly increase the risk of invasive serous ovarian cancers.”” In addition, the statements failed to disclose that: (i) asbestos had repeatedly been found in the Company’s talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, and (iv) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company’s flagship product and reputation.

### **February 2017 False and Misleading Statements**

162. On February 27, 2017, Defendants caused the Company to file its 2016 10-K with the SEC (“2016 10-K”). In its “Cautionary Note Regarding Forward-Looking Statements,” the Company included language regarding “[p]roduct efficacy or safety concerns”:

#### ***Risks Related to Product Liability, Litigation and Regulatory Activity***

Product efficacy or safety concerns, whether or not based on scientific evidence, potentially resulting in product withdrawals, recalls, regulatory action on the part of the U.S. Food and Drug Administration (or international counterparts), declining sales and reputational damage.

163. The Company’s 2016 10-K also discussed the general risks and uncertainties faced by the Company, including legal proceedings:

#### **The Company is subject to significant legal proceedings that can result in significant expenses, fines and reputational damage.**

In the ordinary course of business, Johnson & Johnson and its subsidiaries are subject to numerous claims and lawsuits involving various issues such as patent disputes, product liability and claims that their product sales, marketing and pricing practices violate various antitrust, unfair trade practices and/or consumer protection laws. The most significant of these proceedings are described in Note 21, “Legal Proceedings” under Notes to the Consolidated Financial Statements included in Item 8 of this Report. While *the Company believes it has substantial defenses in these matters*, it is not feasible to predict the ultimate outcome of litigation. The Company could in the future be required to pay significant amounts as a result of settlements or judgments in these matters, potentially in excess of accruals. The resolution of, or increase in accruals for, one or more of these matters in any reporting period could have a material adverse effect on the Company’s results of operations and cash flows for that period. Furthermore, as a result of cost and availability factors, effective November 1, 2005, the Company ceased purchasing third-party product liability insurance.

#### **Product reliability, safety and effectiveness concerns can have significant negative impacts on sales and results of operations, lead to litigation and cause reputational damage.**

Concerns about product safety, whether raised internally or by regulators or consumer advocates, and whether or not based on scientific evidence, can result in safety alerts, product recalls, governmental investigations, regulatory action on the part of the FDA (or its counterpart in other countries), private claims and lawsuits, payment of

finances and settlements, declining sales and reputational damage. These circumstances can also result in damage to brand image, brand equity and consumer trust in the Company's products. Product recalls have in the past, and could in the future, prompt government investigations and inspections, the shutdown of manufacturing facilities, continued product shortages and related sales declines, significant remediation costs, reputational damage, possible civil penalties and criminal prosecution. [Emphasis added].

164. The Company's 2016 10-K disclosed that the Company and some of its subsidiaries were involved in product liability litigation, but also represented that the Company had "substantial defenses":

Johnson & Johnson and certain of its subsidiaries are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. ***While the Company believes it has substantial defenses***, it is not feasible to predict the ultimate outcome of litigation. The Company has established accruals for product liability claims and lawsuits in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated. For certain of these matters, the Company has accrued additional amounts such as estimated costs associated with settlements, damages and other losses. To the extent adverse verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated. Product liability accruals can represent projected product liability for thousands of claims around the world, each in different litigation environments and with different fact patterns. Changes to the accruals may be required in the future as additional information becomes available.

\* \* \*

Claims for personal injury have been made against Johnson & Johnson Consumer Inc. and Johnson & Johnson arising out of the use of JOHNSON'S® Baby Powder. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Lawsuits have been primarily filed in state courts in Missouri, New Jersey and California. In addition, a federal multi-district litigation proceeding has been created for this litigation in the District Court of New Jersey. The Company has established an accrual for defense costs in connection with product liability litigation associated with JOHNSON'S® Baby Powder. Changes to this accrual may be required in the future as additional information becomes available. [Emphasis added].



165. The Company's 2016 10-K also stated that the Company "remain[ed]" committed" to "delivering high quality" and "improving existing products":

Research and development expenditures relate to the processes of discovering, testing and developing new products, *improving existing products*, as well as demonstrating product efficacy and regulatory compliance prior to launch. *The Company remains committed to investing in research and development with the aim of delivering high quality* and innovative products. [Emphasis added].

166. Defendants' statements above were false and misleading. While Defendants boasted of "improving existing products," being "committed to investing in research and development with the aim of delivering high quality . . . products," and of the Company having "substantial defenses," they omitted that: (i) asbestos had repeatedly been found in the Company's talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, and (iv) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation.

#### **May 2017 False and Misleading Statements**

167. On May 8, 2017, Defendants caused the Company to file its first quarter of 2017 Form 10-Q with the SEC. Defendants disclosed that the Company and some of its subsidiaries were involved in product liability litigation, but also represented that the Company had "substantial defenses":

Johnson & Johnson and certain of its subsidiaries are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. While *the Company believes it has substantial defenses*, it is not feasible to predict the ultimate outcome of litigation. The Company has established accruals for product liability claims and lawsuits in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated. For certain of these matters, the Company has accrued additional amounts such as estimated costs associated with settlements,



damages and other losses. To the extent adverse verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated. Product liability accruals can represent projected product liability for thousands of claims around the world, each in different litigation environments and with different fact patterns. Changes to the accruals may be required in the future as additional information becomes available.

\* \* \*

Claims for personal injury have been made against Johnson & Johnson Consumer Inc. and Johnson & Johnson arising out of the use of JOHNSON'S® Baby Powder. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Lawsuits have been primarily filed in state courts in Missouri, New Jersey and California. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the District of New Jersey. The Company has established an accrual for defense costs in connection with product liability litigation associated with JOHNSON'S® Baby Powder. [Emphasis added].

168. Defendants' statements above were false and misleading. While Defendants boasted of having "substantial defenses" to talc-related litigation, they omitted that: (i) asbestos had repeatedly been found in the Company's talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, and (iv) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation.

#### **August 2017 False and Misleading Statements**

169. On August 24, 2017, *The Star* newspaper published an article, "Does talcum powder cause cancer and should you stop using it?" The article quoted the Company's website:

In a post on their website Johnson & Johnson said, "We do understand your concern linked to recent media reports. We want to assure you, however, that we have no higher responsibility than the health and safety of consumers and *the safety of cosmetic talc is supported by decades of scientific evidence.*"

"Since the early 1990s, many research papers and epidemiology studies have evaluated talc and perineal use and these studies have found talc to be safe. In fact, the Nurses' Health Study (2010) and the Women's Health Initiative Observational Cohort (2014), the only two large-scale prospective studies looking at talc and ovarian

cancer, found no causal relationship between talc and ovarian cancer.” [Emphasis added].

170. Defendants’ representation above that “the safety of cosmetic talc is supported by decades of scientific evidence” was false and misleading, as it omitted that the Company knew that some scientific sources were “not as definitive or supportive and could be interpreted as suggesting a causal effect” between ovarian cancer and talc and that “[e]ven some of the studies we cite send mixed messages.” Defendants knew that one of the studies it cited had determined that “perineal talc use may modestly increase the risk of invasive serous ovarian cancers.” In addition, the statements were false and misleading because they omitted that: (i) asbestos had repeatedly been found in the Company’s talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, (iv) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company’s flagship product and reputation, and (v) the Company had misled the FDA in 2016.

171. On August 3, 2017 Defendants caused the Company to file its second quarter of 2017 Form 10-Q with the SEC. Defendants disclosed that the Company and some of its subsidiaries were involved in product liability litigation, but also represented that the Company had “substantial defenses”:

Johnson & Johnson and certain of its subsidiaries are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. While *the Company believes it has substantial defenses*, it is not feasible to predict the ultimate outcome of litigation. The Company has established accruals for product liability claims and lawsuits in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated. For certain of these matters, the Company has accrued additional amounts such as estimated costs associated with settlements, damages and other losses. To the extent adverse verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated. Product liability accruals can represent

projected product liability for thousands of claims around the world, each in different litigation environments and with different fact patterns. Changes to the accruals may be required in the future as additional information becomes available.

\* \* \*

Claims for personal injury have been made against Johnson & Johnson Consumer Inc. and Johnson & Johnson arising out of the use of body powders containing talc, primarily JOHNSONS® Baby Powder. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Lawsuits have been primarily filed in state courts in Missouri, New Jersey and California. Cases filed in federal courts in the United States have been organized as a multidistrict litigation in the United States District Court for the District of New Jersey. The Company has established an accrual for defense costs in connection with product liability litigation associated with body powders containing talc. [Emphasis added].

172. Defendants’ statements above were false and misleading. While Defendants boasted of having “substantial defenses” to talc-related litigation, they omitted that: (i) asbestos had repeatedly been found in the Company’s talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, and (iv) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company’s flagship product and reputation.

#### **September to November 2017 False and Misleading Statements**

173. On September 6, 2017, Defendant Gorsky addressed the talc litigation at a Wells Fargo Healthcare Conference. There, Gorsky assured investors that the Company always puts safety first and that the safety of talc was clearly demonstrated by clinical information, control data, and “100 years of experience”:

*[W]e always put patient and consumers safety first in everything that we do. That being said, we think that **the significant amount of clinical information, control data in this category, both from agencies, such as the NCI as well as the FDA, clearly demonstrates the safety of talc**, and by the way, **from more than a 100 years of experience**. That being said, we were disappointed with some of the early results, for example, in St. Louis. We’re encouraged by some of the recent rulings out of Supreme Court regarding those venues. We’ve also been encouraged by some of the earlier findings in New Jersey. We were disappointed with the first outcome in*

California but, nonetheless, we feel that *we have some strong ground on the field going forward*. And again, *we remain, based upon the data, confident of the position that we're taking*. [Emphasis added].

174. Defendants' representation above that "the safety of talc" was "clearly demonstrate[d]" by "more than a 100 years of experience," was false and misleading. In truth, Defendants acknowledged internally that its talcum powders had not been "safe" for more than 100 years, and indeed, the Company could not even "link cosmetic talc to 100 years of use." The statements also created the impression that the Company's talc has historically been safe, when in fact Defendants knew that when it came to asbestos in the Company's talcum powders, it could not say it was "always" asbestos-free. This statement was also false and misleading because: (i) asbestos had repeatedly been found in the Company's talc and powder, (ii) the Company had attempted to find ways to remove tremolite from its talc, and (iii) never adopted concentration methods that could detect the asbestos.

175. Defendants' representations above that: (i) "the safety of talc" was "clearly demonstrate[d]" by "the significant amount of clinical information [and] control data in this category," including from the FDA, (ii) the Company "always put[s] patient and consumer safety first in everything that [it does]," and (iii) the Company believed it "ha[d] some strong ground on the field going forward" in the talc litigation and "remain[ed], based upon the data, confident of the position [it was] taking," were false and misleading. These statements concealed that: (i) asbestos had repeatedly been found in the Company's talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, (iv) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation, and (v) the Company had misled the FDA in 2016.

176. On September 14, 2017, a *Bloomberg* article entitled “Johnson & Johnson’s Newest Talc Problem? Asbestos” quoted J&J’s website:

Johnson & Johnson declined to comment either on Herford’s suit or the litigation generally. But a statement on the company’s website says: “Since the 1970s, *talc used in consumer products has been required to be asbestos-free*, so *Johnson’s talc products do not contain asbestos*.” [Emphasis added].

177. On September 21, 2017, *Bloomberg* published an article titled “J&J Was Alerted to Risk of Asbestos in Talc in ‘70s, Files Show,” which cited additional statements from the Company:

#### FDA Requirements

“The U.S. Food and Drug Administration requires specific testing to ensure that cosmetic talcum powder is free of asbestos,” Ernie Knewitz, a spokesman for J&J, said in an emailed statement.

“We are confident that our talc products are, and always have been, free of asbestos, based on decades of monitoring, testing and regulation,” Knewitz said. “Historical testing of samples by the FDA, numerous independent laboratories, and numerous independent scientists have all confirmed the absence of asbestos in our talc products.”

\* \* \*

New Brunswick, New Jersey-based *J&J has said the plaintiffs’ allegations aren’t supported by valid scientific evidence*, pointing to a New Jersey state court decision last year tossing out two cases.

The unsealed files were used as part of an April pre-trial deposition given by Joanne Waldstreicher <https://www.jnj.com/office-chief-medical-officer>, J&J’s chief medical officer since 2013. Under questioning by plaintiffs’ lawyer Mark Lanier, *Waldstreicher maintained that J&J’s baby powder products are asbestos free. We have experts that assure there’s no asbestos in our talc*,” she told the lawyer. [Emphasis added].

178. On November 16, 2017, *Law360* published an article entitled “J&J, Talc Supplier Not Liable For Woman’s Asbestos Illness,” citing statements by the Company:

J&J spokesperson Carol Goodrich told Law360 on Thursday that the company stands behind the safety of its baby powder, which it believes is being vindicated in recent court decisions.

“We are pleased with today’s verdict and believe that the dismissal of talc lawsuits in New Jersey and verdict reversals in Missouri and California have forced plaintiff

attorneys to pivot to yet another baseless theory,” she said. “Johnson’s Baby Powder has been around since 1894 and it does not contain asbestos or cause mesothelioma or ovarian cancer.”

179. On November 16, 2017, *Reuters* published a statement by the Company in the article entitled “Johnson & Johnson wins California lawsuit claiming asbestos in talc caused cancer”:

J&J in a statement welcomed the verdict. J&J said it believed that setbacks dealt to individuals pursuing ovarian cancer cases had “forced plaintiff attorneys to pivot to yet another baseless theory.”

***“Johnson’s Baby Powder has been around since 1894 and it does not contain asbestos or cause mesothelioma or ovarian cancer,”*** J&J said. [Emphasis added].

180. Defendants’ statement above that the Company’s “talc products are, and always have been, free of asbestos,” was false and misleading because knew internally that “we cannot say ‘always.’” Similarly, Defendants’ reference to Johnson’s Baby Powder having “‘been around since 1894’” coupled with the representation that “‘it does not contain asbestos or cause mesothelioma or ovarian cancer’” created the impression that the Baby Powder had always been asbestos-free, while J&J acknowledged that “we cannot say ‘always.’” In addition, Defendant Goodrich knew that the Baby Powder had not been safe for the past 100 years and even had in her possession internal discussion stating that “I don’t think we can link cosmetic talc to 100 years of use.” These statements, along with Defendants’ representations that the Company’s “talc products do not contain asbestos” and that the Company’s “baby powder products are asbestos free,” were false and misleading because they concealed that (i) asbestos had repeatedly been found in the Company’s talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, and (iii) the Company never adopted concentration methods that could detect the asbestos.

181. Defendants’ statements above that: (i) the Company’s “‘experts . . . assure there’s no asbestos in [its] talc,’” (ii) “the plaintiffs’ allegations [weren’t] supported by valid scientific evidence” and amounted to a “‘baseless theory,’” (iii) “decades of monitoring, testing and regulation”

assured that J&J's "talc products are, and always have been, free of asbestos," and (iv) "talc used in consumer products has been required to be asbestos-free" "[s]ince the 1970s," were false and misleading. These statements concealed that: (i) asbestos had repeatedly been found in the Company's talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, and (iv) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation. The statement regarding plaintiffs' allegations not being "supported by valid scientific evidence" was false and misleading for the additional reason that the Company knew that in fact some scientific sources, including IARC and the American Cancer Society, were actually "not as definitive or supportive and could be interpreted as suggesting a causal effect" between ovarian cancer and talc and that "[e]ven some of the studies [J&J] cite[d] send[s] mixed messages." For example, Defendants knew one of the studies it cited had concluded that "perineal talc use may modestly increase the risk of invasive serous ovarian cancers."

182. On November 2, 2017, Defendants caused the Company to file its third quarter of 2017 Form 10-Q with the SEC. Defendants acknowledged that the Company and some of the Company's subsidiaries were involved in product liability litigation, but also represented that the Company had "substantial defenses":

Johnson & Johnson and certain of its subsidiaries are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. While *the Company believes it has substantial defenses*, it is not feasible to predict the ultimate outcome of litigation. The Company has established accruals for product liability claims and lawsuits in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated. For certain of these matters, the Company has accrued additional amounts such as estimated costs associated with settlements, damages and other losses. To the extent adverse verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be



probable and can be reasonably estimated. Product liability accruals can represent projected product liability for thousands of claims around the world, each in different litigation environments and with different fact patterns. Changes to the accruals may be required in the future as additional information becomes available.

\* \* \*

Claims for personal injury have been made against Johnson & Johnson Consumer Inc. and Johnson & Johnson arising out of the use of body powders containing talc, primarily JOHNSONS® Baby Powder. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Lawsuits have been primarily filed in state courts in Missouri, New Jersey and California. Cases filed in federal courts in the United States have been organized as a multidistrict litigation in the United States District Court for the District of New Jersey. The Company has established an accrual for defense costs in connection with product liability litigation associated with body powders containing talc. [Emphasis added].

183. Defendants' statements above were false and misleading.

184. While defendants boasted of having "substantial defenses" to the talc-related litigation, they omitted that: (i) asbestos had repeatedly been found in the Company's talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, and (iv) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation.

#### **January 2018 False and Misleading Statements**

185. On January 16, 2018, *Fair Warning* published a story entitled "Baby Powder Battles: Johnson & Johnson Internal Documents Reveal Asbestos Worries." *Fair Warning* reported that ***J&J "has said its powders are perfectly safe and could not have caused mesothelioma."***

186. *Fair Warning* also reported additional false and misleading statements made by the Company:

***Reports of asbestos contamination have "never been proven to be correct,"*** declared John Hopkins, a toxicologist and former J&J executive.



Defense lawyers made a plausible case for a different cause of Herford's mesothelioma: the aggressive radiation treatments she received for breast cancer in 1998. Therapeutic radiation is one of the only suspected causes of mesothelioma other than asbestos.

Following its victory, *J&J blasted the "baseless theory" that its powders could be harmful. "Johnson's Baby Powder has been around since 1894 and it does not contain asbestos or cause mesothelioma,"* according to the company's statement.

187. Defendants' statements above that Johnson's Baby Powder has "'been around since 1894'" and that "'it does not contain asbestos or cause mesothelioma,'" were false and misleading, creating the false impression that the Baby Powder had always been asbestos-free, while the Company recognized internally that it could not say "'always.'" This statement was also false and misleading because it concealed that: (i) asbestos had repeatedly been found in the Company's talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, and (iii) the Company never adopted concentration methods that could detect the asbestos.

188. Similarly, Defendants' representations that it was a "'baseless theory'" that the Company's products could be harmful, that reports of asbestos contamination "'have 'never been proven to be correct,'" and that the Company's "powders are perfectly safe, and could not have caused mesothelioma," were false and misleading. These statements concealed that: (i) asbestos had repeatedly been found in the Company's talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, and (iv) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation.

#### **February to April 2018 False and Misleading Statements**

189. On February 5, 2018, in an article entitled "Johnson & Johnson falls on report that lawsuits could expose potentially damaging documents," CNBC quoted a Company spokesman:

In a statement, a J&J spokesman pointed to a California judge ruling in favor of J&J in November in a lawsuit by a woman who said she developed mesothelioma after using the company's talc-based products. He said the company would continue to defend its position in future cases.

***“We are confident that our talc products are, and always have been, free of asbestos, based on decades of monitoring, testing and regulation dating back to the 1970s,” he said. “Historical testing of samples by the FDA, numerous independent laboratories, and numerous independent scientists have all confirmed the absence of asbestos in our talc products.”*** [Emphasis added].

190. Defendants' statement that J&J's “talc products are, and always have been, free of asbestos,” was false and misleading because Defendants knew internally that it could not “say ‘always.’” This statement, along with defendants' representation that “decades of monitoring [and] testing” “dating back to the 1970s” supported the notion that the products have “always . . . been . . . free of asbestos,” were false and misleading because they concealed that (i) asbestos had repeatedly been found in the Company's talc and powder, (ii) the Company had attempted to find ways to remove tremolite from its talc, and (iii) the Company never adopted concentration methods that could detect the asbestos.

191. Defendants' statements that: (i) “the absence of asbestos in our talc products” had been “confirmed” by “[h]istorical testing of samples by the FDA, numerous independent laboratories, and numerous independent scientists,” and (ii) “decades of . . . regulation dating back to the 1970s” assured that the Company's “talc products are, and always have been, free of asbestos” were also false and misleading. These statements concealed that: (i) asbestos had repeatedly been found in the Company's talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, (iv) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation, and (v) the Company had misled the FDA in 2016.

192. On February 21, 2018, Defendants caused the Company to file its 2017 10-K with the SEC. In its “Cautionary Note Regarding Forward-Looking Statements,” the Company included language regarding “[p]roduct efficacy or safety concerns”:

***Risks Related to Product Liability, Litigation and Regulatory Activity***

Product efficacy or safety concerns, whether or not based on scientific evidence, potentially resulting in product withdrawals, recalls, regulatory action on the part of the U.S. Food and Drug Administration (or international counterparts), declining sales and reputational damage.

193. The Company’s 2017 10-K also discussed the general risks and uncertainties faced by the Company, including legal proceedings:

**The Company is subject to significant legal proceedings that can result in significant expenses, fines and reputational damage.**

In the ordinary course of business, Johnson & Johnson and its subsidiaries are subject to numerous claims and lawsuits involving various issues such as patent disputes, product liability and claims that their product sales, marketing and pricing practices violate various antitrust, unfair trade practices and/or consumer protection laws. The most significant of these proceedings are described in Note 21, “Legal Proceedings” under Notes to the Consolidated Financial Statements included in Item 8 of this Report. While *the Company believes it has substantial defenses in these matters*, it is not feasible to predict the ultimate outcome of litigation. The Company could in the future be required to pay significant amounts as a result of settlements or judgments in these matters, potentially in excess of accruals. The resolution of, or increase in accruals for, one or more of these matters in any reporting period could have a material adverse effect on the Company’s results of operations and cash flows for that period. Furthermore, as a result of cost and availability factors, effective November 1, 2005, the Company ceased purchasing third-party product liability insurance.

**Product reliability, safety and effectiveness concerns can have significant negative impacts on sales and results of operations, lead to litigation and cause reputational damage.**

Concerns about product safety, whether raised internally or by litigants, regulators or consumer advocates, and whether or not based on scientific evidence, can result in safety alerts, product recalls, governmental investigations, regulatory action on the part of the FDA (or its counterpart in other countries), private claims and lawsuits, payment of fines and settlements, declining sales and reputational damage. These circumstances can also result in damage to brand image, brand equity and consumer trust in the

Company's products. Product recalls have in the past, and could in the future, prompt government investigations and inspections, the shutdown of manufacturing facilities, continued product shortages and related sales declines, significant remediation costs, reputational damage, possible civil penalties and criminal prosecution. [Emphasis added].

194. The Company's 2017 10-K acknowledged that it and some of its subsidiaries were involved in product liability litigation, but also represented that the Company had "substantial defenses":

Johnson & Johnson and certain of its subsidiaries are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. While *the Company believes it has substantial defenses*, it is not feasible to predict the ultimate outcome of litigation. The Company has established accruals for product liability claims and lawsuits in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated. For certain of these matters, the Company has accrued additional amounts such as estimated costs associated with settlements, damages and other losses. To the extent adverse verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated. Product liability accruals can represent projected product liability for thousands of claims around the world, each in different litigation environments and with different fact patterns. Changes to the accruals may be required in the future as additional information becomes available.

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Claims for personal injury have been made against Johnson & Johnson Consumer Inc. and Johnson & Johnson arising out of the use of body powders containing talc, primarily JOHNSONS® Baby Powder. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Lawsuits have been primarily filed in state courts in Missouri, New Jersey and California. Cases filed in federal courts in the United States have been organized as a multidistrict litigation in the United States District Court for the District of New Jersey. The Company has established an accrual for defense costs in connection with product liability litigation associated with body powders containing talc. [Emphasis added].

195. The Company's 2017 10-K also stated that the Company "remain[ed]" committed" to "delivering high quality" and "improving existing products":

Research and development expenditures relate to the processes of discovering, testing and developing new products, upfront payments and milestones, ***improving existing products***, as well as demonstrating product efficacy and regulatory compliance prior to launch. ***The Company remains committed to investing in research and development with the aim of delivering high quality*** and innovative products. [Emphasis added].

196. Defendants’ statements were false and misleading. While Defendants boasted of “improving existing products,” being “committed to investing in research and development with the aim of delivering high quality . . . products,” and of the Company having “substantial defenses,” they omitted that: (i) asbestos had repeatedly been found in the Company’s talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, and (iv) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company’s flagship product and reputation.

197. On February 26, 2018, at the Committee Encouraging Corporate Philanthropy CEO Investor Forum, Defendant Gorsky told investors:

I think the real special sauce at Johnson & Johnson is our credo. And to think that, that document – and, again, this thing was written more than 75 years ago. In fact, this is the 75th anniversary of ***Our Credo***. Long before corporate social responsibility was in the day-to-day lexicon or vernacular, and the fact that the son of our founder took the time to write this out in such an eloquent way, a little over 300 words, talking about commitments, I think it’s just incredibly inspiring. And ***it’s really formed kind of the value system, the backdrop and in fact, I’d say the strategy outline for Johnson & Johnson in everything we do***. [Emphasis added].

198. On April 12, 2018, the *New York Daily News* reported on statements made by Defendant Goodrich, in response to the Lanzo trial verdict:

J&J denied that its products contain cancer-causing toxins and says it plans to appeal. ***“Johnson’s Baby Powder has been used for more than 120 years and it does not contain asbestos or cause mesothelioma,”*** said spokeswoman Carol Goodrich. ***“We believe that once the full evidence is reviewed, this decision will be reversed.”*** [Emphasis added].

199. Then, on April 26, 2018, at the Company's Annual Shareholders Meeting, Defendant Gorsky told investors:

And Our Credo, it dates back to 1943, authored by the then Chairman Robert Wood Johnson II, the son of one of the founding Johnson brothers. And it was right before Johnson & Johnson became a public company. And on that day, at that moment, Johnson & Johnson's moral compass as a family, as a company, was formally documented, and that has sustained us for these past 75 years.

Our Credo, well, *it stood the test of time*, unyielding in challenging times and unforgotten in times of great success. It balances opportunity with responsibility. And *we are united and inspired by Our Credo, and we live into those responsibilities it outlines each and every day*. It reminds us that our very first responsibility is to customers and patients. And it compels us to deliver on our responsibilities to our employees, our communities, our environment and to you, our shareholders. And it's because of our strong credo foundation and being broadly based in health care that we are committed to profoundly changing the trajectory of health for humanity.

To accomplish this, we intend to: first, invest in areas for enduring long-term impact; position our businesses to deliver strong, consistent and sustainable results; lead with agility and a sense of urgency needed to tackle the world's changing needs; to create life-enhancing innovations, all while empowering and inspiring diverse employees and an inclusive culture; and continue to use our reach and size for good. Now through the many decades of change that we've seen in the health care industry's experience, *Johnson & Johnson has continued to advance with the evolution of science and technology*, whether it was through our pioneering development of sterile surgery at the turn of the 20th century or today, as we develop a differentiated robotic-assisted surgery platform in orthopaedics [sic] or build novel regimens to boost T cells and train them to recognize and actually attack cancer and focus to create a preventive vaccine for HIV/AIDS. [Emphasis added].

200. At the April 26, 2018 Shareholders Meeting, Defendant Gorsky also told investors:

*Now at Johnson & Johnson, we are committed to meeting the needs of our stakeholders, as defined in Our Credo, the doctors, the nurses and patients and the mothers and fathers and all others who use our products*; our employers, our suppliers, and the communities in which we live and work. We're also committed to providing positive economic impact wherever we do business as well as delivering a fair return to our shareholders.

*Now our people and our partners have been focused on that one thing, the thing that is the most important, the most personal to every individual and every family on earth: their health and well-being*. And for the second year in a row, we were named to the annual Fortune Magazine Change the World List, which spotlights the 50 top

global companies that have had a positive social impact through their activities that are part of their core business strategy.

\* \* \*

We recognize that to lead the next frontier of health, well, it's a big commitment. But we are ready, willing and able to take on this task. ***Guided by our purpose-driven strategies and values that are rooted in our credo, we will always put the needs and well-being of the people we serve first.*** [Emphasis added].

201. Defendants' statements that (i) its Credo was "the value system, the backdrop and in fact . . . the strategy outline for Johnson & Johnson in everything" it does, (ii) its Credo "stood the test of time, unyielding in challenging times and unforgotten in times of great success," (iii) the Company is "united and inspired by Our Credo, and we live into those responsibilities it outlines each and every day," (iv) the Company is "committed to meeting the needs of our stakeholders, as defined in Our Credo, the doctors, the nurses and patients and the mothers and fathers and all others who use our products," (v) the Company has "been focused on that one thing, the thing that is the most important, the most personal to every individual and every family on earth: their health and well-being," and (vi) the Company "will always put the needs and well-being of the people we serve first," were false and misleading. In truth, Defendants had and continued to conceal that: (i) asbestos had repeatedly been found in the Company's talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, (iv) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation, and (v) the Company had misled the FDA in 2016.

202. Defendant Goodrich's statements that (i) "Johnson's Baby Powder has been used for more than 120 years and it does not contain asbestos or cause mesothelioma," and (ii) "once the full evidence is reviewed, [the Lanzo verdict] will be reversed," were false and misleading. In truth,



Goodrich knew that the Company's talcum powders had not been "safe" for over 100 years, and indeed, the Company could not even "link cosmetic talc to 100 years of use." Goodrich also knew that when it came to asbestos in the Company's talcum powders, they could not "say 'always'" asbestos free. These statements were false and misleading because they omitted that: (i) asbestos had repeatedly been found in the Company's talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, and (iv) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation.

203. Defendant Gorsky's statement that J&J "has continued to advance with the evolution of science and technology" was false and misleading because it concealed that the Company: (i) never adopted concentration methods that could detect the asbestos in the Company's talcum powders, and (ii) continued to sell its talcum powders despite knowing that asbestos had repeatedly been found in the Company's talc and powders.

#### **May 2018 False and Misleading Statements**

204. On May 1, 2018, Defendants caused the Company to file its Form 10-Q with the SEC for the first quarter of 2018. Defendants disclosed that the Company and some of its subsidiaries were involved in product liability litigation, but also represented that the Company had "substantial defenses":

Johnson & Johnson and certain of its subsidiaries are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. While *the Company believes it has substantial defenses*, it is not feasible to predict the ultimate outcome of litigation. The Company has established accruals for product liability claims and lawsuits in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated. For certain of these matters, the Company has accrued additional amounts such as estimated costs associated with settlements,



damages and other losses. To the extent adverse verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated. Product liability accruals can represent projected product liability for thousands of claims around the world, each in different litigation environments and with different fact patterns. Changes to the accruals may be required in the future as additional information becomes available.

\* \* \*

Claims for personal injury have been made against Johnson & Johnson Consumer Inc. and Johnson & Johnson arising out of the use of body powders containing talc, primarily JOHNSONS® Baby Powder. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Lawsuits have been primarily filed in state courts in Missouri, New Jersey and California. Cases filed in federal courts in the United States have been organized as a multidistrict litigation in the United States District Court for the District of New Jersey. The Company has established an accrual for defense costs only in connection with product liability litigation associated with body powders containing talc. [Emphasis added].

205. Defendants' statements were false and misleading. While Defendants boasted of having "substantial defenses" to talc-related litigation, they omitted that: (i) asbestos had repeatedly been found in the Company's talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, and (iv) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation.

206. On May 16, 2018, *CNBC* published a video interview with Defendant Gorsky regarding the re-launch of the Company's Baby Products line. In the interview, Defendant Gorsky made the following statements:

[Gorsky:] [I]t's a re-launch, and we're really focusing on . . . the changing needs of the Millennial mom, and we realize that over the past few years that we probably got a little bit behind the curve, but what you're going to hear about today is how we totally reformulated the brand where we're changing and making sure we're using more natural ingredients. *We've taken out many of the concerning products, or ingredients, that . . . mothers didn't want in their products*, things like surfactants, parabens, and other . . . ingredients. And we've also made sure that we're really creating a conversation with the Millennial mom. So yeah, *we're really excited about*

*the re-launch of Baby, and we think what it does is it makes it current*, it makes it relevant, but at the same time it doesn't lose . . . that basic smell, that basic touch that you expect from the Johnson's Baby line.

[Reporter:] Well this comes after a couple years you've had some . . . pretty extreme headlines coming out of the lawsuits around the talc baby powder product. You know, I've heard from some folks they've lost trust in the brand because of those headlines that they're seeing and the concerns of some link to cancer from the talc baby products. I talked with Jorge Mesquita, your Head of Consumer, who said you defend the brand, the science shows there is no link to cancer and that wasn't the driver behind the re-launch. But how do you keep consumers' trust, perhaps win back their trust, in the midst of all these headlines?

[Gorsky:] Well look, we certainly understand that. And *when it comes to babies, safety, high quality has got to be first and foremost in everything that we do*. And so what we're talking about today is how do we take these legacy brands and really better position them for the future. You know, for example, *let's start with clinical data and information. You know, J&J, we have conducted more than 90% of the clinical trials*. And the Millennial mom, they have a high expectation about data. *They want to know, frankly, do these products work. Are they safe and are they effective. And the fact that we are able to produce that kind of information behind our brands, that we share it with the broader community, is really important*. So those are some of the steps that we're taking . . . we think to make sure the brands do well today but also into the future. [Emphasis added].

207. On May 16, 2018, at the Consumer and Medical Devices Business Review,

Defendant Gorsky told investors:

So now what I'd like to do is take just a few moments to highlight the strengths and the opportunities for each of our different business segments. . . .

And look, *we're not afraid to acknowledge areas that we need to fix. We want to talk about that, learn from them to make us better going forward*. And we firmly believe that Johnson & Johnson is strongly positioned for continued and future growth.

\* \* \*

So in closing, first and foremost, I want to thank you for being here today and investing your time in Johnson & Johnson. . . .

And *you've got our absolute commitment that we'll hold ourselves accountable and execute on the strategic plans that you're going to hear about today, fulfill all of our Credo responsibilities where we always keep the customer and patients at the*

*center of everything we do* and ultimately profoundly change the trajectory of health for humanity. [Emphasis added].

208. At the May 16, 2018, Consumer and Medical Devices Business Review, Global Chief Technology Officer Josh Ghaim told investors:

We have designed JOHNSON'S with everything a mom wants for 100% gentle new classics. ***While our ingredients have been always been safe, our new formulations contain no unwanted ingredients.*** To meet the needs of new moms today, more than 90% of the ingredients in our formulations are natural. We have built superior experience with no-residue formulas, professional reassurance through dermatologist and pediatrician testing, all with unique claims based on our body of baby skin science. [Emphasis added].

209. And at the same May 16, 2018 Conference, Executive VP and Worldwide Chairman Jorge Mesquita responded to a question from an analyst regarding talc:

With regard to talc, sorry. What I can assure you is ***we've been through this extensively, and we are 100% sure that our talc product is safe.*** And we will continue to defend our brand, we will continue to defend our product. [Emphasis added].

210. Defendants' statements that: (i) "when it comes to babies" safety and high quality are "first and foremost in everything that we do," (ii) the Company is "not afraid to acknowledge areas that [it] need[s] to fix" and the Company "want[s] to talk about that" and "learn from them to make [itself] better going forward," and (iii) the Company "hold[s] [itself] accountable" on "fullfill[ing] all of our Credo responsibilities where we always keep the customer and patients at the center of everything we do," were false and misleading. Rather than putting safety first, acknowledging and learning from its mistakes, or holding themselves accountable to the Company's Credo, Defendants continued to conceal the truth regarding its Baby Powder, including that: (i) asbestos had repeatedly been found in the Company's talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, (iv) the Company had purposely influenced and manipulated regulators and

scientists in order to protect the Company's flagship product and reputation, and (v) the Company had misled the FDA in 2016.

211. Defendants' statement that the Company's ingredients "have . . . always been safe," was false and misleading, as the Company acknowledged internally that "we cannot say 'always'" with regards to the Company's talcum powders being asbestos-free. This statement that: (i) the Company had "taken out many of the concerning . . . ingredients, that . . . mothers didn't want in their products," (ii) "the re-launch of Baby" makes the product line "current," (iii) the Company's large number of clinical trials show that the Baby products are safe, and (iv) the Company's "new formulations contain no unwanted ingredients," were false and misleading for other reasons. These statements concealed that: (i) asbestos had repeatedly been found in the Company's talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, and (iii) the Company never adopted concentration methods that could detect the asbestos.

212. Defendants' statement that after going through the information "extensively," the Company is "100% sure that our talc product is safe," was also false and misleading. In truth, Defendants knew that some scientific sources were actually "not as definitive or supportive and could be interpreted as suggesting a causal effect" between ovarian cancer and talc and that "[e]ven some of the studies [it] cite[d] send[s] mixed messages." Defendants knew that even one of the studies cited by the Company had concluded that "'perineal talc use may modestly increase the risk of invasive serous ovarian cancers.'" In addition, the statement was false and misleading because it failed to disclose that: (i) asbestos had repeatedly been found in the Company's talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, and (iv) the Company had purposely

influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation.

213. On May 21, 2018, at the UBS Global Healthcare Conference, the Company discussed its global supply chain:

We did make an announcement that we're taking some actions to further optimize our network and I'll explain to you why that is. But about 5 years ago, we had changed our approach at JNJ to how we manage our supply chain around the globe to enable us to have much more global consistency, to drive better flexibility in our supply chain, but also to ensure that ***we've got the right quality and compliance in all of our manufacturing sites around the world, both internal and external.*** [Emphasis added].

214. On May 21, 2018, in an article entitled "Johnson & Johnson to relaunch baby-care line after its 20% sales decline," a Company spokesman stated: "***We are absolutely certain that science shows that our talcum product is safe,*** and we will defend our brand and defend our product."

215. And on May 28, 2018, in an article entitled "Juries Weigh Cases Over Alleged Harms of Johnson & Johnson Baby Powder," the *Wall Street Journal* reported statements made by the Company:

Johnson & Johnson said it would appeal and "continue to defend the safety of our product because ***it does not contain asbestos or cause mesothelioma.***" The company said ***over the past 50 years, multiple scientific evaluations, including from the U.S. Food and Drug Administration, have been conducted and "none have found that the talc in Johnson's Baby Powder contains asbestos."*** [Emphasis added].

216. Defendants' statement that J&J now had "the right quality and compliance in all of [its] manufacturing sites around the world," was false and misleading, as Defendants had knowingly failed to adopt an effective method for testing its talc, despite numerous occasions of asbestos being found in the Company's talc and powders.

217. Defendants' statements that: (i) the Company is "absolutely certain that science shows that our talcum product is safe," and (ii) Johnson's Baby Powder "does not contain asbestos

or cause mesothelioma,” as “multiple scientific evaluations” “over the past 50 years” including by the FDA have not found asbestos in Johnson’s Baby Powder, were also false and misleading. These statements concealed that: (i) asbestos had repeatedly been found in the Company’s talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, (iv) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company’s flagship product and reputation, and (v) the Company had misled the FDA in 2016. In addition, while Defendants said publicly that it was “absolutely certain that science shows” the safety of talc, it knew that some scientific sources were actually “not as definitive or supportive and could be interpreted as suggesting a causal effect” between ovarian cancer and talc and that at least one had concluded that “perineal talc use may modestly increase the risk of invasive serous ovarian cancers.”

### **July to August 2018 False and Misleading Statements**

218. On July 12, 2018, Defendants caused the Company to issue a statement regarding the Ingham case verdict:

Johnson & Johnson is deeply disappointed in *the verdict, which was the product of a fundamentally unfair process* that allowed plaintiffs to present a group of 22 women, most of whom had no connection to Missouri, in a single case all alleging that they developed ovarian cancer. The result of the verdict, which awarded the exact same amounts to all plaintiffs irrespective of their individual facts, and differences in applicable law, reflects that *the evidence in the case was simply overwhelmed by the prejudice* of this type of proceeding.

*Johnson & Johnson remains confident that its products do not contain asbestos and do not cause ovarian cancer and intends to pursue all available appellate remedies. Every verdict against Johnson & Johnson in this court that has gone through the appeals process has been reversed and the multiple errors present in this trial were worse than those in the prior trials which have been reversed.* [Emphasis added].

219. On July 12, 2018, *Bloomberg* reported on comments made by Defendant Goodrich via email:<sup>14</sup>

The company will appeal, Carol Goodrich, a spokeswoman, said in an email. The verdict “*was the product of a fundamentally unfair process* that allowed plaintiffs to present a group of 22 women, most of whom had no connection to Missouri, in a single case all alleging that they developed ovarian cancer,” she said.

That each plaintiff and her family members were awarded \$25 million for their losses “irrespective of their individual facts, and differences in applicable law, reflects that *the evidence in the case was simply overwhelmed by the prejudice* of this type of proceeding,” Goodrich added.

\* \* \*

#### ‘Multiple Errors’

*The company’s products don’t contain asbestos and don’t cause ovarian cancer*, she said. Goodrich predicted the verdict would be reversed. “The multiple errors present in this trial were worse than those in the prior trials which have been reversed.” [Emphasis added].

220. Defendants’ statements that the verdict was “the product of a fundamentally unfair process” where the “evidence . . . was simply overwhelmed by the prejudice,” while the truth was that the Company’s products “do not contain asbestos and do not cause ovarian cancer,” were false and misleading. In truth, Defendants knew that: (i) asbestos had repeatedly been found in the Company’s talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, and (iv) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company’s flagship product and reputation. In addition, Goodrich knew that the Company could not “say ‘always’” when it comes to Johnson’s Baby Powder being asbestos-free.

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<sup>14</sup> “J&J’s \$4.69 Billion Talc Loss Hands Investors a What-Next Moment.”



And while Defendant Goodrich promised that the Company's talc did not cause ovarian cancer, she knew that some scientific sources were actually "not as definitive or supportive and could be interpreted as suggesting a causal effect" between ovarian cancer and talc and that at least one had concluded that "perineal talc use may modestly increase the risk of invasive serous ovarian cancers."

221. On July 17, 2018, during a conference call discussing the Company's 2Q18 results, Defendant Gorsky told investors:

Before I provide some perspective by business segment, it's important to begin where I usually do, emphasizing that *we are always guided by our credo*; and this year, we proudly celebrate its 75th anniversary. *Our credo is as relevant today as the day it was written*. Balancing opportunity and responsibility, *we're united and inspired by* our credo and we live in the responsibilities it outlines each and every day.

\* \* \*

Additionally, we are revitalizing our baby business. In fact, beginning this month, our newly formulated Johnson's Baby products have started to ship to retailers across the United States. We continue to strengthen and expand our portfolio of iconic, *science-based and professionally endorsed products*, and we have a number of planned launches in the second half of this year. We also believe that this will drive top line growth that will be met with even greater bottom line growth as we continue to improve our productivity and margins.

\* \* \*

Regarding the recent St. Louis talcum powder lawsuit and verdict. As you know, our baby powder is a trusted product that we sold to families for over 100 years, and Johnson & Johnson is deeply disappointed in this verdict. Now *we remain confident that our products do not contain asbestos and do not cause ovarian cancer*, and we intend to pursue all available appellate remedies. In fact, every verdict against Johnson & Johnson in this court that has gone through the appeals process has been reversed.

Additionally, I want to emphasize that *preeminent scientific and regulatory bodies, including the National Cancer Institute, the U.S. Food and Drug Administration have fully reviewed the full body of scientific evidence on multiple occasions and found that it does not support the allegation that talc causes ovarian cancer*. Like



previous appeals, we are confident that there are multiple grounds for reversal of this jury verdict and that, ultimately, the case will be reversed.

\* \* \*

We believe in a bright and successful future, where virtually anything that can be imagined, can be accomplished through a laser-like focus on innovation, execution and our customers, which ultimately drives superior long-term performance. And while we're focused on all of this, ***we also remain committed to fulfilling our credo responsibilities*** and striving to profoundly change the trajectory of Health for Humanity. [Emphasis added].

222. Defendants' statement that the Company is "always guided by our credo," was false and misleading, as it concealed that: (i) asbestos had repeatedly been found in the Company's talc and powders but the Company failed to inform the public, (ii) the Company had thought about seeking a profitable patent for a method of removing tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos despite knowing that it was necessary to find any asbestos present, (iv) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation, and (v) the Company had misled the FDA in 2016.

223. Defendants' statements that: (i) the Company remained "committed to fulfilling our credo responsibilities," (ii) the Credo was "as relevant today as the day it was written," and (iii) the Company was "inspired by our credo" and "live[d] in the responsibilities it outlines each and every day," were false and misleading. In truth, Defendants failed to live up to the Credo by continuing to conceal the truth about Johnson's Baby Powder, including that: (i) asbestos had repeatedly been found in the Company's talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, (iv) the Company had purposely influenced and manipulated regulators and scientists in order to

protect the Company's flagship product and reputation, and (v) the Company had misled the FDA in 2016.

224. Defendant's statement that J&J had "science-based and professionally endorsed products," was false and misleading as (i) asbestos had repeatedly been found in the Company's talc and powders and (ii) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation.

225. Defendants' reliance on the fact that Baby Powder has been "sold to families for over 100 years" and representation that the Company is "confident that our products do not contain asbestos and do not cause ovarian cancer," were false and misleading. Defendants had acknowledged internally that talc did not have 100 years of safe use and they could not "say 'always'" when it comes to Baby Powder being asbestos-free. In addition, these statements concealed that: (i) asbestos had repeatedly been found in the Company's talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, and (iii) the Company never adopted concentration methods that could detect the asbestos.

226. Defendants' statement that "scientific and regulatory bodies" such as the FDA had "fully reviewed the full body of scientific evidence on multiple occasions and found that it does not support the allegation that talc causes ovarian cancer" was false and misleading. In truth, (i) the Company had lied to the FDA as recently as 2016 regarding asbestos in its talc, and (ii) the scientific and regulatory bodies never had "the full body of scientific evidence" because the Company never disclosed that asbestos had been found in the Company's talc and powders on numerous occasions. The statement was also false and misleading because the Company knew that some scientific sources were actually "not as definitive or supportive and could be interpreted as suggesting a causal effect" between ovarian cancer and talc and that at least one had concluded that "perineal talc use may

modestly increase the risk of invasive serous ovarian cancers.” Finally, the statement was false and misleading in that it omitted that: (i) asbestos had repeatedly been found in the Company’s talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, and (iv) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company’s flagship product and reputation.

227. On August 2, 2018, Defendants caused the Company to file its 2Q18 Form 10-Q with the SEC. Defendants disclosed that the Company and some of its subsidiaries were involved in product liability litigation, but also represented that the Company had “substantial defenses”:

Johnson & Johnson and certain of its subsidiaries are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. While *the Company believes it has substantial defenses*, it is not feasible to predict the ultimate outcome of litigation. The Company has established accruals for product liability claims and lawsuits in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated. For certain of these matters, the Company has accrued additional amounts such as estimated costs associated with settlements, damages and other losses. To the extent adverse verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated. Product liability accruals can represent projected product liability for thousands of claims around the world, each in different litigation environments and with different fact patterns. Changes to the accruals may be required in the future as additional information becomes available.

\* \* \*

Personal injury claims alleging that talc causes cancer have been made against Johnson & Johnson Consumer Inc. and Johnson & Johnson arising out of the use of body powders containing talc, primarily JOHNSONS® Baby Powder. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Lawsuits have been primarily filed in state courts in Missouri, New Jersey and California. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the District of New Jersey. The Company has successfully defended a number of these cases but there have been verdicts against the Company, including a recent jury verdict of \$4.7

billion. The Company believes that it has strong grounds on appeal to overturn these verdicts. The Company has established an accrual for defense costs only in connection with product liability litigation associated with body powders containing talc. [Emphasis added].

228. Defendants' statements were false and misleading. While Defendants boasted of having "substantial defenses" to talc-related litigation, they omitted that: (i) asbestos had repeatedly been found in the Company's talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, and (iv) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation.

#### **October 2018 False and Misleading Statements**

229. On October 31, 2018, Defendants caused the Company to file its third quarter 2018 Form 10-Q with the SEC. Defendants acknowledged that the Company and some of its subsidiaries were involved in product liability litigation, but also represented that the Company had "substantial defenses":

Johnson & Johnson and certain of its subsidiaries are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. While *the Company believes it has substantial defenses*, it is not feasible to predict the ultimate outcome of litigation. The Company has established accruals for product liability claims and lawsuits in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated. For certain of these matters, the Company has accrued additional amounts such as estimated costs associated with settlements, damages and other losses. To the extent adverse verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated. Product liability accruals can represent projected product liability for thousands of claims around the world, each in different litigation environments and with different fact patterns. Changes to the accruals may be required in the future as additional information becomes available.

\* \* \*

Personal injury claims alleging that talc causes cancer have been made against Johnson & Johnson Consumer Inc. and Johnson & Johnson arising out of the use of body powders containing talc, primarily JOHNSONS® Baby Powder. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Lawsuits have been primarily filed in state courts in Missouri, New Jersey and California. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the District of New Jersey. The Company has successfully defended a number of these cases but there have been verdicts against the Company, including a recent jury verdict of \$4.7 billion. The Company believes that it has strong grounds on appeal to overturn these verdicts. The Company has established an accrual for defense costs only in connection with product liability litigation associated with body powders containing talc. [Emphasis added].

230. Defendants' statements were false and misleading. While Defendants boasted of having "substantial defenses" to talc-related litigation, they omitted that: (i) asbestos had repeatedly been found in the Company's talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, and (iv) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation.

### **DEFENDANTS' KNOWLEDGE**

#### **Defendant Gorsky**

231. Defendant Gorsky knew or recklessly disregarded that his statements and the statements made by the Company in public filings with the SEC were false and misleading. As alleged herein, Defendant Gorsky admitted to paying very close attention to the Company's quality issues, including the allegations surrounding the Company's talcum powders specifically, and he also represented that he was intensely focused on whether the Company was acting in accordance with its corporate Credo. These admissions included the following:

- At the Company's April 2012 annual meeting, Defendant Gorsky spent over 30 minutes on Our Credo, promising that he was determined to keep it as the foundation at J&J and repeatedly assuring investors that the Company was adhering to the corporate credo's values.

- On January 21, 2014, Defendant Gorsky admitted to having knowledge about whether the “Chief Medical and Chief Quality Officers [were] setting new benchmarks for medical safety” and whether the Company was “*monitoring the use of our end market products*” to “*ensu[re] that they are safe.*”
- On January 12, 2015, Defendant Gorsky provided that “[q]uality and safety” was J&J’s “*number-one priority*” and that he and his team at the Company had “over the last few years” “made a number of changes . . . to *make sure that we addressed any of the outstanding issues that we were facing.*” By the time Defendant Gorsky made this admission, the Company had suffered the first verdict linking talc to ovarian cancer and was facing mounting claims brought by federal class action plaintiffs, state court litigants, and the Attorney General of Mississippi. The safety of the Company’s talcum powders was thus a well-known “outstanding issue[.]”
- On April 23, 2015, Defendant Gorsky admitted the importance of Johnson’s Baby Powder and the Company’s other consumer brands, noting that “our consumer, our iconic consumer brands have been, and continue to be, perhaps *the greatest connection that we have with people, with consumers all over the world.*”
- On September 6, 2017, Defendant Gorsky admitted to paying attention to “the significant amount of clinical information [and] control data” involving talc and talcum powders, including from agencies like the National Cancer Institute (“NCI”) and FDA, and claimed to have *sufficient knowledge* to form an opinion on “the safety of talc.” Defendant Gorsky also made clear that *he had assessed sufficient data surrounding J&J’s talcum powders* in order to form an opinion about J&J’s defense in the talcum powder litigation.
- On September 6, 2017, Defendant Gorsky *admitted to closely following the ovarian cancer litigation developments*, referencing St. Louis as one of “the early results,” as well as “earlier findings in New Jersey” and “the first outcome in California.”
- On May 16, 2018, Defendant Gorsky admitted to having *knowledge about the ingredients in J&J’s Baby products and whether J&J had “taken out many of the concerning . . . ingredients*, that . . . mothers didn’t want in their products.”
- On May 16, 2018, Defendant Gorsky admitted to reviewing the Company’s “clinical data and information” regarding talc’s safety.
- On May 16, 2018, Defendant Gorsky promised that he and J&J had an “absolute commitment [to] hold ourselves accountable and . . . fulfill all of our Credo responsibilities where we always keep the customer and patients at the center of everything we do.”

- On July 17, 2018, Defendant Gorsky admitted to knowing whether J&J is “always guided by our credo” and remains committed to it, and whether the Credo is still relevant.
- On July 17, 2018, Defendant Gorsky *admitted to having knowledge about J&J’s baby products, including whether they are “science-based* and professionally endorsed.”
- On July 17, 2018, Defendant Gorsky *admitted to paying attention to the talc litigation*, including whether J&J’s products contained asbestos or caused ovarian cancer. In addition, Defendant Gorsky claimed to know whether scientific and regulatory bodies had “fully reviewed the full body of scientific evidence.”

232. Defendant Gorsky’s knowledge is further bolstered by his actions which illustrate that he paid special attention to product quality issues, including the ongoing litigation surrounding the Company’s talcum powders. Indeed, from his first day on the job as CEO, Defendant Gorsky knew investors were deeply concerned over quality issues and the Company’s reputation.

233. In addition, the June 6, 2017 email to Defendant Gorsky and the Board that included a *“deck under the heading of ‘Update on Talc Litigation’ in Tab 7 that discusses reputational risk”* illustrates that Defendant Gorsky was made aware of, and his attention was on, the issues surrounding talc.

234. Defendant Gorsky’s knowledge is further evidenced by the fact that, as a long time executive in the consumer and pharma industries, he had a *heightened understanding of the troubles that revelation of unethical and/or illegal business conduct could bring* to the Company and himself. He had been “actively involved” at Janssen when “Janssen managers effectively embraced off-label promotion” and Janssen exhibited “especially unscrupulous” behavior, that “recklessly put at risk the health of some of the most vulnerable members of society” and showed “blatant disregard for systems and laws.” This conduct led to Janssen’s \$2.2 billion settlement with the Department of Justice.



235. Similarly, Defendant Gorsky was warned by the FDA while he was at Novartis that representations made by the company “suggested that [the product in question was] safer . . . than ha[d] been demonstrated.” This experience alerted Defendant Gorsky to the importance of not making false and misleading statements regarding product safety. Defendant Gorsky was deposed regarding the Company’s DePuy unit, which would later be hit with a jury verdict of over \$1 billion and had “personal involvement” in preparing corporate communications regarding the defective hip implants at issue in the case.

### **Defendant Goodrich**

236. Defendant Goodrich knew that her statements, and corporate statements that she created and contributed to were false and misleading. Defendant Goodrich personally worked on the language to be included on the “Our Safety & Care Commitment” website, which was available as of January 7, 2014. And while the “Our Safety & Care Commitment” website touted talc’s “safety profile,” “long history of safe use,” and use “for over 100 years,” Defendant Goodrich knew that the use of talc had not actually been safe for 100+ years, and may not have even occurred with regards to “cosmetic talc.” In addition, although the website implied that the Company’s talc products have always been asbestos-free, Defendant Goodrich knew that the Company could not accurately “say ‘always.’” She also knew or was reckless in making additional false misleading statements, including: (i) on May 2, 2016, that the Company “has provided consumers with a safe choice for cosmetic powder products” “[f]or over 100 years,” (ii) on November 16, 2017, that “Johnson’s Baby Powder has been around since 1894 and it does not contain asbestos or cause mesothelioma or ovarian cancer,” and (iii) in April 2018, that “Johnson’s Baby Powder has been used for more than 120 years and it does not contain asbestos.”

237. Defendant Goodrich also knew that it was false and misleading to represent (i) on the “Our Safety & Care Commitment” website, that talc’s purported safety was supported by “more than 30 years of research,” examination by “[v]arious agencies and governmental bodies” supported talc’s safety, and “[m]any research papers and epidemiology studies” “published since the early 1990s” “have found talc to be safe,” (i) on February 23, 2016, that talc’s safety is “supported by decades of scientific evidence,” and that J&J believed this to be true, and (iii) on May 2, 2016, that “30 years of studies by medical experts around the world . . . continue to support” cosmetic talc’s safety, and that “[m]ultiple scientific and regulatory reviews have determined that talc is safe for use . . . and the labeling on Johnson’s Baby Powder is appropriate.” Defendant Goodrich in fact knew that other scientific sources not cited on “Our Safety & Care Commitment” website could actually “be interpreted as suggesting a causal effect” between talc and ovarian cancer, including from IARC and the American Cancer Society. She also knew that “[e]ven some of the studies” cited by the Company on its website sent “mixed messages,” including a study recognizing that ““perineal talc use may modestly increase”” the risk of ovarian cancer.

### **Defendant Casalvieri**

238. Defendant Casalvieri knew that her statements claiming that scientific studies, “assessments by external experts,” and the Company’s “company testing” supported talc’s safety, were false and misleading. She *admitted to examining “assessments by external experts”* and having *knowledge of J&J’s “company testing,”* and emphasized that “[a]s a toxicologist in our Consumer business,” “*my job is to make certain a product is safe.*” Thus, Casalvieri would have been informed of the very facts making her statement misleading. By holding herself out as an expert on the safety of J&J’s talc products and “assur[ing] women and caregivers who use our talc products” of their safety, Casalvieri publicly represented that she fully understood the possible dangers of talc

when making her false and misleading statements. Defendant Casavieri's scienter is further bolstered by the fact that she was featured on the updated "Our Safety & Care Commitment" website available as of December 25, 2015, which represented that "[w]e *have carefully assessed all available data on talc*," including the "body of research and clinical evidence."

239. In addition to these admissions and representations, Casavieri's knowledge is also evidenced by her direction of the Company's fraudulent conduct in 2005. Indeed, Defendant Casavieri *directed J&J's project "to defend talc,"* which included "*develop[ing] documents* that scientifically support the lack of a relationship of talc and ovarian cancer," including secretly funding a meta-study supportive of talc. Defendant Casavieri also knew, but failed to disclose, that the Company had worked *under her direction* "to assure a good outcome" for talc against the NTP. Her centrality to that effort is clear: she was *personally congratulated* for her work when the NTP withdrew talc from consideration as a possible carcinogen. Defendant Casavieri knew, but failed to disclose, that the decision by the NTP "was *a direct result of [J&J's] efforts* in coordination with Luzenac and CTFA," efforts which she herself directed. As the director of the project to defend talc, Defendant Casavieri also received detailed updates from Steve Mann regarding the day-to-day of these efforts, including the Company's attempt at getting its own experts embedded in the IARC process. Finally, Defendant Casavieri worked closely with Mann to "defend talc" within less than a year after Mann was informed that Forensic Analytical and a news station had discovered asbestos in Johnson's Baby Powder. It is implausible that Defendant Casavieri would not also have known of this finding.

### **Defendant Glasgow**

240. Defendant Glasgow knew that her statements were false and misleading. On January 24, 2017, Glasgow emphasized that she and others at the Company meticulously assembled and reviewed all of the available data on the safety of talc, which included “decades of scientific work”:

When it comes to the safety of the products we make, we’re just like you. . . ***We want all the information we can get. We seek out the guidance of experts and we monitor the latest science*** to see if it impacts any of our products. ***We also listen to the people who use our products*** so we can take their experiences into account. . . .

***[T]here is no information more important than our research on scientific data and safety. We go beyond the findings of a single study because we must ensure we’ve assembled all of the available data*** from multiple scientific areas to reach conclusions based on evidence. One opinion or study can’t outweigh ***decades of conclusive, scientific, evidence-based findings***. As a scientist and, equally important, as a parent myself, I can tell you the science is clear: Cosmetic talc is, and has been, safe for use in consumer products.

We are all mothers, fathers, and consumers ourselves; we understand and take seriously our responsibility to give you the information you need to make your own decisions. We choose to include these ingredients not simply because we’ve used them for decades. We include them because ***decades of scientific work support their safety***. [Emphasis added].

241. In addition, Defendant Glasgow represented that she and the rest of the Company “feel, as scientists, an obligation to continue to take our research to the next level by ***looking at all the science***.” Glasgow held herself out as having reviewed “30 years of scientific studies and regulatory reviews,” along with “the medical facts and science” regarding the Company’s talcum powder products. Similarly, she represented that she had reviewed the studies, “science, research and clinic evidence” regarding the safety of talc. In sum, Defendant Glasgow knew or recklessly disregarded the wealth of scientific information within the Company regarding the dangers of its talcum powders.

### **Defendant Sneed**

242. Defendant Sneed knew that his statements were false and misleading. As VP of Global Corporate Affairs, Sneed was involved with the Company’s public relations and knew

that checking the accuracy of corporate statements was vitally important. Indeed, he admitted that “[t]he reputation of J&J is very important to us” and that “[w]e take it very seriously” when he spoke to investors on April 25, 2013. He also represented that he knew about (i) the Company’s efforts to “get past some of the challenges we’ve had as a business,” (ii) what the Company does when it makes “mistakes,” (iii) “the values that are behind J&J,” (iv) whether the Company “really embraced transparency,” and (v) whether the Company had a history of “car[ing] unconditionally for others.” Thus, he knew or recklessly disregarded that his statements were false and misleading and omitted material information.

#### **Additional Information Supporting Knowledge**

243. Defendants’ knowledge is further established by the detailed allegations regarding the importance of Johnson’s Baby Powder to the Company’s overall business and reputation, the Company’s purposely inadequate test methods, the Company’s massive fraudulent scheme and pervasive corporate misconduct, and numerous red flags that the Company had received.

#### **Johnson’s Baby Powder Was Absolutely Critical to Consumers’ Trust and the Company’s Overall Business and Reputation**

244. As alleged herein, the Company has repeatedly recognized the vital importance of Johnson’s Baby Powder for the Company’s business. Because the Company is in the business of selling consumer goods, drugs, and medical devices, its success depends on consumer trust. And because Baby Powder is “*a primary link to the positive J&J name in the public mind,*” a recognition that the talc used in it was carcinogenic “*would have a major ripple effect*” for the Company. Indeed, in 2018, the Company’s counsel admitted that Johnson’s Baby Powder “is about the trust of Johnson & Johnson,” because “[J&J] know[s] that the people who use this product are mothers and babies . . . and these are Johnson & Johnson’s customers,” so “this is about trust.” In further recognition of the dire stakes, in 2017, the Company’s Board of Directors spent an entire slide

deck on an “Update on Talc Litigation” that discussed “*reputational risk*.” And in *sworn testimony*, the Company’s longstanding corporate representative recognized the truth that “*it would be very, very bad for business* if it ever came out that the baby powder or any of Johnson & Johnson’s talc products ever contained asbestos.”

245. The Company has also provided additional detail regarding the heightened corporate concern over Johnson’s Baby Powder. According to *the Company’s own admissions*, “despite the depth and breadth of its product lines,” the Company remains known as “the Baby Company.” And Johnson’s Baby Powder has been ““the cornerstone of [the] baby products franchise.”” Indeed, the Company admitted that Johnson’s Baby Powder is a ““flagship product,” ““sacred cow,” “institution,” “the most widely recognized fragrance in the United States,” and “one of the most familiar and trusted products in the world.” The Company’s longtime corporate representative has even admitted *under oath* that Johnson’s Baby Powder is among “the top one or two products that people think of when they think of J&J.”

246. Other admissions by the Company illustrate the depth and reach of the public’s relationship with Johnson’s Baby Powder, and thus the potentially devastating impact to the Company’s reputation, were the truth to surface. For example, the Company admits that “[i]f you’ve ever cared for a baby, you’ve probably had JOHNSON’S Baby Powder in your home.” Thus, if it were to come out that the Baby Powder contained asbestos, millions of parents would face the horrifying realization that they had unknowingly exposed their children to asbestos through a Johnson & Johnson product. The betrayal of trust for millions of consumers would be all the more disturbing because of the Company’s longstanding efforts to convince the public to think of the Company “as a lifetime friend of the family” and to create an association between Baby Powder and “the parent-infant bond.”

247. And, following the *Reuters* report's revelations, financial analysts specifically recognized the significant negative impact to the Company's overall business and reputation. For example, on December 14, 2018, CFRA lowered its opinion on the Company from "buy" to "hold" and dropped their price target by \$30 per share. The CFRA report made clear that the new information and analysis revealed by *Reuters* would cause "significant damage" to the Company's "valuable brand name" because consumer trust is "critical" to the Company's overall "success." As CFRA explained: "We see today's news potentially impacting sales of everything from baby shampoo to prosthetic hips. Given these elevated risks, we no longer feel JNJ shares are attractive at recent prices." And, in a January 25, 2019 report, CFRA again emphasized the importance of the reputational damage: "Brand-name *reputation is critically important for the success of [J&J's] Consumer segment*, in our view." And, recognizing the significant negative impact to the Company's overall business and reputation, CFRA noted: "Due to the importance of brand power and consumer trust, we think *allegations from a Reuters story published in December 2018 could have a meaningful negative impact on JNJ's Consumer segment, as well as the Medical Devices segment to a lesser extent.*"

**IN REPURCHASING STOCK, THE COMPANY RELIED  
ON THE FALSE OR MISLEADING STATEMENTS**

248. In repurchasing common stock, the Company relied on Defendants false or misleading statements, either directly or through the "fraud on the market" doctrine articulated in *Basic Inc. v. Levinson*, 485 U.S. 224 (1988), and *Halliburton Co. v. Erica P. John Fund, Inc.*, 134 S. Ct. 2398 (2014), or through the doctrine articulated in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972).

249. The Company justifiably expected Defendants to disclose material information as required by law and SEC regulations in the Company's periodic filings with the SEC and in



statements made to the investing public. The Company would not have purchased its securities at artificially inflated prices had Defendants disclosed all material information known to them or that was so obvious it should have been known to them, as detailed herein. Thus, reliance by the Company should be presumed with respect to Defendants omissions of material information as established by the *Affiliated Ute* presumption of reliance.

250. Additionally, the “fraud on the market” presumption applies to Defendants’ misstatements of material facts or failures to disclose material facts.

251. At all relevant times, the market for J&J stock was efficient market for the following reasons, among others:

- (a) J&J stock met the requirements for listing, and was listed and actively traded on NYSE, a highly efficient and automated market;

- (b) As a regulated issuer, J&J filed periodic public reports with the SEC and NYSE;

- (c) J&J’s common-stock trading value was substantial on a daily basis, exceeding millions of shares per day throughout the Relevant Period;

- (d) J&J regularly and publicly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services;

- (e) J&J was followed by several securities analysts employed by major brokerage firm(s) who wrote reports which were distributed to the sales force and certain customers of

their respective brokerage firm(s). Each of these reports was publicly available and entered the public marketplace; and

(f) The market price of J&J's stock reacted rapidly to new information entering the market.

252. As a result of the foregoing, the market for J&J stock promptly digested current information regarding the Company from all publicly available sources and reflected such information in the price of J&J's common stock. The foregoing facts indicate the existence of an efficient market for trading of J&J's stock and support application of the fraud-on-the-market doctrine.

253. J&J relied on the integrity of the market price for the repurchase of its common stock and is entitled to a presumption of reliance with respect to the Defendants' misstatements and omissions alleged herein.

254. Had J&J known of the material adverse information not disclosed by Defendants or been aware of the truth behind Defendants' material misstatements, the Company would not have purchased J&J stock at artificially inflated prices.

**NEITHER THE STATUTORY "SAFE HARBOR" NOR THE "BESPEAKS CAUTION" DOCTRINE APPLIES TO THE MISREPRESENTATIONS**

255. Neither the safe-harbor provision of the Private Securities Litigation Reform Act of 1995 ("PSLRA") nor the judicially created "bespeaks caution" doctrine applicable to forward looking statements under certain circumstances applies to any of the false or misleading statements pleaded herein. None of the subject statements constituted a forward-looking statement; rather, they were historical statements or statements of purportedly current facts and conditions at the time the statements were made.

256. Alternatively, to the extent any of the false or misleading statements pleaded herein could be construed as forward-looking statements, they were not accompanied by any meaningful cautionary language identifying important fact that could cause actual results to differ materially from those in the purportedly forward-looking statements. Further, to the extent the PSLRA's safe harbor would otherwise apply to any forward-looking statements pleaded herein, Defendants are liable for those false or misleading forward-looking statements pleaded herein because, at the time each such statement was made, the speaker knew the statement was false or misleading, or the statement was authorized and/or approved by an executive officer of J&J who knew that the statement was materially false or misleading when made. None of the historic or present tense statements made by Defendants were assumptions underlying or relating to any plan, projection, or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by Defendants expressly related to, or stated to be dependent on, those historic or present tense statements when made.

257. On July 21, 2014, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to \$5.0 billion of the Company's Common Stock

258. On October 13, 2015, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to \$10.0 billion of the Company's Common Stock

#### **DERIVATIVE AND DEMAND FUTILITY ALLEGATIONS**

259. Plaintiff brings this action derivatively in the right and for the benefit of the Company to redress injuries suffered and to be suffered as a direct and proximate result of the breaches of fiduciary duties and gross mismanagement by Defendants.

260. Plaintiff will adequately and fairly represent the interests of the Company and its shareholders in enforcing and prosecuting its rights and has retained counsel competent and experienced in derivative litigation.

261. Plaintiff is a current owner of the Company stock and has continuously been an owner of Company stock during Defendants' wrongful course of conduct alleged herein. Plaintiff understands her obligation to hold stock throughout the duration of this action and is prepared to do so.

262. In accordance with New Jersey law, on October 23, 2019 and November 15, 2019, Plaintiff sent the Demand to the Company Board to investigate, address, remedy, and commence proceedings against certain of the Company's current and former officers and directors for mismanagement and breaches of fiduciary duties. To date, the Board has refused to substantively respond to the Demand and, upon information and belief, refused to take any action demanded.

263. Plaintiff has not made any demand on the other stockholders of the Company to institute this action since such demand would be a futile and useless act for at least the following reasons:

- (a) the Company is a publicly held company with over 2.6 billion shares outstanding and thousands of stockholders as of July 24, 2019;

- (b) making demand on such a number of stockholders would be impossible for plaintiff who has no way of finding out the names, addresses, or phone numbers of stockholders; and

(c) making demand on all stockholders would force plaintiff to incur excessive expenses, assuming all stockholders could be individually identified.

**FIRST CAUSE OF ACTION**

**(Against The Individual Defendants For Breach Of Fiduciary Duties)**

264. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

265. Defendants owe the Company fiduciary obligations. By reason of their fiduciary relationships, the Individual Defendants owed and owe the Company the highest obligation of good faith, fair dealing, loyalty, and due care.

266. The Individual Defendants violated and breached their fiduciary duties of care, loyalty, reasonable inquiry, and good faith.

267. The Individual Defendants engaged in a sustained and systematic failure to properly exercise their fiduciary duties. Among other things, the Individual Defendants breached their fiduciary duties of loyalty and good faith by allowing the Company to improperly misrepresent the Company's publicly reported financials and internal controls. These actions could not have been a good faith exercise of prudent business judgment to protect and promote the Company's corporate interests.

268. As a direct and proximate result of the Individual Defendants' failure to perform their fiduciary obligations, the Company has sustained significant damages. As a result of the misconduct alleged herein, the Individual Defendants are liable to the Company.

269. As a direct and proximate result of the Individual Defendants' breach of their fiduciary duties, the Company has suffered damage, not only monetarily, but also to its corporate image and goodwill. Such damage includes, among other things, costs associated with defending

securities lawsuits, severe damage to the share price of the Company, resulting in an increased cost of capital, the waste of corporate assets, and reputational harm.

## **SECOND CAUSE OF ACTION**

### **(Against The Individual Defendants for Waste of Corporate Assets)**

270. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above, as though fully set forth herein

271. The wrongful conduct alleged regarding the issuance of false and misleading statements was continuous, connected, and on-going throughout the Relevant Period. It resulted in continuous, connected, and ongoing harm to the Company.

272. As a result of the misconduct described above, the Individual Defendants wasted corporate assets by, *inter alia*: (i) paying excessive compensation, bonuses, and termination payments to certain of its executive officers; (ii) awarding self-interested stock options to certain officers and directors; and (iii) incurring potentially millions of dollars of legal liability and/or legal costs to defend Defendants' unlawful actions.

273. As a result of the waste of corporate assets, the Individual Defendants are liable to the Company.

274. Plaintiff, on behalf of J&J, has no adequate remedy at law.

## **THIRD CAUSE OF ACTION**

### **(Against The Individual Defendants For Unjust Enrichment)**

275. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

276. By their wrongful acts and omissions, the Individual Defendants were unjustly enriched at the expense of and to the detriment of J&J. The Individual Defendants were unjustly

enriched as a result of the compensation and director remuneration they received while breaching fiduciary duties owed to J&J.

277. Plaintiff, as a stockholder and representative of J&J, seeks restitution from these defendants, and each of them, and seeks an order of this Court disgorging all profits, benefits, and other compensation obtained by these defendants, and each of them, from their wrongful conduct and fiduciary breaches.

278. Plaintiff, on behalf of J&J, has no adequate remedy at law.

#### **FOURTH CAUSE OF ACTION**

##### **(Against The Individual Defendants for Violations of Section 10(b) of the Exchange Act and SEC Rule 10b-5)**

279. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

280. During the Relevant Period, the Individual Defendants disseminated or approved public statements that failed to disclose that (i) asbestos had repeatedly been found in the Company's talc and powders, (ii) the Company had attempted to find ways to remove tremolite from its talc, (iii) the Company never adopted concentration methods that could detect the asbestos, (iv) the Company had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation, and (v) the Company had misled the FDA. Thus, the price of the Company's shares was artificially inflated due to the deception of the Individual Defendants. Despite this artificial inflation in the price of the Company's shares, the Individual Defendants caused and/or allowed the Company to repurchase many millions of shares of Company stock, thereby causing financial harm to the Company.

281. As alleged herein, the Individual Defendants acted with scienter in that they knew that the public documents and statements issued or disseminated in the name of the Company were



materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, Individual Defendants, by virtue of their receipt of information reflecting the true facts regarding J&J, their control over, and/or receipt and/or modification of J&J's allegedly materially misleading statements and/or their associations with the Company which made them privy to confidential proprietary information concerning J&J participated in the fraudulent scheme alleged herein.

282. The Individual Defendants knew and/or recklessly disregarded the false and misleading nature of the information which they caused to be disseminated to the investing public. The fraudulent scheme described herein could not have been perpetrated during the Relevant Period without the knowledge and complicity or, at least, the reckless disregard of the personnel at the highest levels of the Company, including the Individual Defendants.

283. Based on their roles at J&J, each of the Individual Defendants would have been involved with, or knowledgeable about, the wrongdoing alleged herein.

284. At a minimum, the Individual Defendants failed to review or check information that they had a duty to monitor or ignored obvious signs that their statements were materially false and misleading or contained material omissions. Given the nature and extent of the problems at J&J, the Individual Defendants knew and/or recklessly disregarded the extent and scope of their statements during the Relevant Period.

285. Likewise, the Individual Defendants, by virtue of their high-level positions with the Company, directly participated in the management of the Company, were directly involved in the day-to-day operations of the Company at the highest levels, and were privy to confidential

proprietary information concerning the Company and its business, operations, financial statements, and financial condition, as alleged herein. The Individual Defendants had the ultimate authority over and were involved in drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein, were aware, or recklessly disregarded, that the false and misleading statements regarding the Company were being issued, and approved or ratified these statements, in violation of the federal securities laws.

286. The allegations above also establish a strong inference that J&J, as an entity, acted with corporate scienter throughout the Relevant Period because its officers, management, and agents had actual knowledge of the misrepresentations and omissions of material facts set forth herein (for which they had a duty to disclose), or acted with reckless disregard for the truth because they failed to ascertain and to disclose such facts, even though such facts were available to them. Such material misrepresentations and/or omissions were done knowingly or with recklessness, and without a reasonable basis, for the purpose and effect of concealing J&J's true operating condition and present and expected financial performance from investors. By concealing these material facts from investors, J&J maintained and/or increased its artificially inflated common stock price throughout the Relevant Period.

287. As such Individual Defendants caused the Company to violate section 10(b) of the Exchange Act and SEC Rule 10b-5 in that they: (i) employed devices, schemes, and artifices to defraud; and (ii) made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

288. As a result of the Individual Defendants' misconduct, the Company is suffering litigation expense and reputational harm in the marketplace in violation of section 10(b) of the Exchange Act and SEC Rule 10b-5.

**REQUEST FOR RELIEF**

**WHEREFORE**, Plaintiff demands judgment as follows:

- A. Determining that this action is a proper derivative action maintainable under law, and that demand is excused;
- B. Awarding, against all Defendants and in favor of the Company, the damages sustained by the Company as a result of Defendants' breaches of their fiduciary duties;
- C. Directing the Company to take all necessary actions to reform and improve its corporate governance and internal procedures, to comply with the Company's existing governance obligations and all applicable laws and to protect the Company and its investors from a recurrence of the damaging events described herein;
- D. Awarding to Plaintiff the costs and disbursements of the action, including reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses; and
- E. Granting such other and further relief as the Court deems just and proper.

**JURY DEMAND**

Plaintiff demands a trial by jury on all issues so triable

Dated: January 23, 2020

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